MEDICAID BUDGET INITIATIVES

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIRST CONGRESS

SECOND SESSION

SEPTEMBER 10 AND 14, 1990

Serial No. 101–206

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CONTENTS

Hearings held on: Page
- September 10, 1990 1
- September 14, 1990 253

Testimony of:
- Ansak, Marie-Louise, executive director, On Lok 309
- Bristow, Lonnie R., member, board of trustees, American Medical Association 696
- Cooper, Hon. Jim, a Representative in Congress from the State of Tennessee 10, 260
- Dinkins, David N., mayor, city of New York 33
- Durbin, Hon. Richard J., a Representative in Congress from the State of Illinois 26
- Galbraith, Susan, director, Coalition on Alcohol and Drug Dependent Women and Their Children 285
- Gans, John A., chief executive officer, American Pharmaceutical Association 693
- Gehring, Richard, chair, board of directors, Alzheimer's Association 96
- Hanley, Ray, chairman, State Medicaid Directors' Association of the American Public Welfare Association 131
- Hill, Barbara, president, Johns Hopkins Health Program, on behalf of Group Health Association of America 453
- Ingram, Robert A., executive vice president, Glaxo, Inc 648
- Johnson, Kay, director, health division, Children's Defense Fund 41
- Jones, William E., executive director, American Association of University Affiliated Programs for Persons With Developmental Disabilities 100
- Kennelly, Hon. Barbara, a Representative in Congress from the State of Connecticut 21
- McGuire, Jean F., executive director, AIDS Action Council 103
- Melden, Michael, staff attorney, National Health Law Program 428
- Miller, Hon. George, a Representative in Congress from the State of California 11
- Mossinghoff, Gerald J., president, Pharmaceutical Manufacturers Association 572
- Parks, James, chief, Medi-Cal Drug Discount Program, California Department of Health Services 523
- Pelrine, Alicia, group director, human resources, National Governors' Association 112
- Pryor, Hon. David, a U.S. Senator from the State of Arkansas 256
- Rector, John M., vice president of government affairs and general counsel, National Association of Retail Druggists 688
- Rosenbaum, Sara, director of programs and policy, Children's Defense Fund 733
- Roslewicz, Thomas D., Deputy Inspector General for Audit Services, Department of Health and Human Services 380
- Sabo, Hon. Martin Olav, a Representative in Congress from the State of Minnesota 19
- Shapiro, Mildred, commissioner, associate committee for medical assistance, New York State 490
- Shikles, Janet L., director, Health Financing and Policy Issues, Human Resources Division, General Accounting Office 367
- Siegel, David, medical director, Health Alliance Plan of Michigan 367

Testimony of—Continued | Page

- Slattery, Hon. Jim, a Representative in Congress from the State of Kansas 7
- Swift, Hon. Al, a Representative in Congress from the State of Washington 6
- Tallon, James R., Jr., majority leader, New York State Assembly, on behalf of the Robert Wood Johnson Foundation 490
- Taylor-Little, Carol, on behalf of the National Conference of State Legislatures 116
- Thompson, Lawrence H., Assistant Comptroller General, Human Resources Division, General Accounting Office 512
- Toews, James D., on behalf of the National Association of State Mental Retardation Program Directors, Inc 145
- Torda, Phyllis, director, health policy, Families USA Foundation 498
- Weiss, Hon. Ted, a Representative in Congress from the State of New York 16
- Wilensky, Gail R., Administrator, Health Care Financing Administration. 157
- Wolfe, Sidney M., director, Public Citizen Health Research Group 268
- Zabriskie, John L., president, Merck, Sharp & Dohme 625
- Ziegler, Ronald L., president and chief executive officer, National Association of Chain Drug Stores 655

Material submitted for the record by:

- Affordable Financing for Longterm Care, statement 748
- American Psychiatric Association, statement 750
- American Psychological Association, et al., statement 248
- Bayh, Evan, Governor, State of Indiana, statement 487
- California Children's Hospital Association, statement 752
- California Legislature, Steven Thompson, director, Assembly Office of Research, statement 763
- Community Legal Services, Inc., statement 765
- Detroit Association of Black Organizations, statement 779
- Hall, Hon. Tony P., a Representative in Congress from the State of Ohio, statement 226
- Health and Human Services, letter from Gail Wilensky to Chairman Waxman and additional responses to questions of August 15 212
- Healthcare Management Alternatives, Inc., letter dated September 24, 1990 from Anthony Welters to Chairman Waxman 781
- Health Insurance Association of America, statement 792
- Industrial Biotechnology Association, statement 801
- National Black Caucus of State Legislatures, statement 803
- National Data Corporation, statement 807
- Panetta, Hon. Leon E., a Representative in Congress from the State of California, statement 4
- Texas Department of Human Services, statement 815
- Voice of the Retarded, letter dated September 7, 1990 from Marty Pratt, president, to Chairman Waxman 41

MEDICAID BUDGET INITIATIVES

MONDAY, SEPTEMBER 10, 1990

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Health and the Environment,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:55 a.m., in room 2322, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. Waxman. Good morning. The meeting of the subcommittee will please come to order.

This morning, this subcommittee will hold the first day of 2 days of hearings on Medicaid budget initiatives.

The purpose of these hearings is to prepare the subcommittee to respond to whatever directives are issued to the Energy and Commerce Committee under the terms of the agreement reached at the budget summit.

The subcommittee has before it six main initiatives:

The Medicaid Infant Mortality Amendments, H.R. 3931, which would implement a campaign promise of President Bush to phase in Medicaid coverage for pregnant women and infants with incomes below 185 percent of the Federal poverty level;

The Medicaid Child Health Amendments, H.R. 3932, which would implement a campaign promise of President Bush to phase in Medicaid coverage for all children in families with income below 100 percent of poverty;

The Medicaid Frail Elderly Community Care Amendments, H.R. 3933, which would allow States to cover home and community-based services for the low-income functionally disabled elderly;

The Medicaid community rehabilitation services amendments of 1990, H.R. 3934, which would allow States to cover only community-based services for Medicaid-eligible individuals with mental retardation, epilepsy, or cerebral palsy;

The Medicaid Hospice Amendments, H.R. 3935, which would require States to cover hospice services under the Medicaid programs, and the Medicaid AIDS and HIV Amendments, H.R. 4080, which would allow States to extend Medicaid coverage for preventive drugs and physician services to lower income individuals infected with the HIV virus.

Many of the subcommittee members are joined in sponsoring these initiatives.

All of the details of these initiatives were adopted by this committee and by the full House last year.

This past May, the House adopted a budget resolution setting aside the necessary resources for all six of these bills, $285 million in fiscal year 1991, and $7.55 billion over the next 5 years.

There has been obviously some water over the dam since May.

In July, the administration has revised its estimates of the Federal budget deficit upward to $168.8 billion.

Because this is more than $100 billion over the Gramm-Rudman target for the fiscal year starting in 3 weeks, a devastating sequester looms.

OMB projects a reduction of 38.4 percent in domestic programs.

We have thousands of troops in Saudi Arabia, and it does not appear that they will be leaving in the near future.

The cost of the savings and loan bailout continues to rise and the economy appears to be on the brink of a recession.

While these developments change the budgetary and political context within which we must operate, they do not reduce the need for improvements in the Medicaid program.

We will hear this morning from our colleagues, from the mayor of the Nation's largest city, and from other witnesses, about how much needs to be done to make the Medicaid program responsive to the needs of the poor in 1990.

I know that we can reduce the budget deficit without cutting means-tested entitlements like Medicaid, and I am hopeful that the negotiators of the budget summit will set aside some additional resources for long overdue improvements in the program.

Before we call on our first panel, I want to recognize members of the subcommittee for opening statements and I will first call upon our colleague, Mr. Scheuer.

Mr. SCHEUER. Thank you very much, Mr. Chairman.

I want to thank all of our colleagues lined up there in the front row and other witnesses today for taking their valuable time to testify before our subcommittee this morning.

All of these proposals that we are going to hear are important and have been thoughtfully designed, but I would like to direct my attention at one proposal that I think deserves particular consideration.

H.R. 2499, introduced by Representative Barbara Kennelly, is a necessary precondition to permit 10 States to conduct a long-term care demonstration project funded by the Robert Wood Johnson Foundation of New Jersey.

New York is one of those States.

In New York, a year of nursing home care costs between $30,000 and $40,000 a year.

Most people who need nursing home care eventually find themselves dependent on Medicaid, which requires them to so called spend down; that is, to deplete their life savings before they are eligible for benefits.

It is absurd, and it is unacceptable that an individual could work hard for their entire life, set aside a fund for his or her retirement, then become—then have to be impoverished and go on welfare in order to take advantage of facilities and services and aids that flow from the Medicaid system.

With the passage of Representative Kennelly's bill, my State and nine others are proposing to offer an alternative.

Last year, the Senate did pass the necessary waiver that would allow Medicaid money to go to people who did not meet income and asset guidelines that forced recipients to spend down and use up all of their resources first.

It is time that the House followed suit and give the States the flexibility they need to conduct this important demonstration.

I believe that Barbara Kennelly has the vehicle for us, and I appreciate all the thought and effort that you have put into this magnificent piece of legislation.

I am looking forward to all of the testimony.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. Thank you very much, Mr. Chairman.

Very briefly, millions of low-income Americans fall between the gaps in Medicaid, and in particular, I hope this session we can do something about bringing uniformity to the crazy quilt of Medicaid eligibility.

I think it is outrageous that a child of five, for example, is guaranteed coverage, but not his 80-year-old brother or sister.

If you don't have children, you can't get Medicaid coverage no matter how poor you are.

Now, I think we have an opportunity with several of the bills that are before the panel this session to address these concerns, and I am particularly hopeful that the frail elderly legislation can move forward this time.

I think it is the next logical step in developing a long-term care policy for our country.

It simply would give States the option of using earmarked funds, Medicaid earmarked funds for institutional care for home health care, and I think it is long overdue that that legislation be enacted.

Finally, I would just like to mention that I think the Medicaid program is being ripped off by the big drug companies.

The Government is not getting what amounts to most-favored-nation status in terms of purchasing prescription medicine, and I am very hopeful we can get that legislation passed.

I look at the front row. We have a cavalcade of stars in the Congress coming before us, and I will break my orating off and look forward to hearing our colleagues.

Mr. WAXMAN. Thank you, Mr. Wyden.

Our first panel consists of eight of our colleagues from the House, each of whom has supported the subcommittee's efforts to improve the Medicaid program.

I would like to ask each of you to come forward and take your places at the table:

Al Swift is a member of our full committee, a principal author of the Patient Self-Determination Act of 1990, H.R. 5067, and has led the effort to assure that consumers have the information they need to make intelligent decisions about their health care;

Jim Slattery is a member of both our full committee and the Budget Committee, a sponsor of the Medicaid Child Health Amendments of 1990, H.R. 3931, and has worked vigorously in the Budget Committee to assure adequate funding for this vital initiative.

Jim Cooper, another member of our full committee, is like Mr. Slattery, a leading advocate for rural health care with his sponsorship of the Medicaid share protection amendments.

He is leading the congressional effort to preserve State prerogatives in determining how to finance their share of the Medicaid program.

George Miller is chairman of the Select Committee on Children, Youth and Families and has used that position with great effect to increase the Federal Government's investment in our Nation's children.

Over the years, no one has been more supportive of this subcommittee's efforts to expand Medicaid coverage for low-income, pregnant women and children.

Ed Weiss, chairman of the Subcommittee on Human Resources and Intergovernmental Relations of the Government Operations Committee, a subcommittee on which both I and Congresswoman Collins have the pleasure of standing on.

His oversight will, I believe, lead to improvements in the quality of physician services that Medicaid buys.

As a member of both the Appropriations and Budget Committees, Marty Sabo spends a lot of time with the Federal Government's financial statements, but he knows a good investment when he sees one, and he has fought hard for improvements in existing health care programs and has authored his own comprehensive health care reform proposal.

Barbara Kennelly serves on the Ways and Means Committee's Subcommittee on Human Resources, where she has worked diligently to improve the AFDC and SSI cash assistance programs on which Medicaid eligibility is based.

One of the Medicaid eligibility categories even bears her name, the "Kennelly widows."

She is also a leading proponent for expanding access by the elderly to quality long-term care.

Last, but definitely not least, Dick Durbin, a member of the Budget Committee, has been one of the staunchest supporters of this subcommittee's efforts to reduce infant mortality in this country.

Not only is he a cosponsor of H.R. 3931, the Medicaid Infant Mortality Amendments, but he has also authored his own initiative, the Medicaid Outreach and Child Health Act of 1990.

Before we begin the testimony, I want to thank publicly the three members of the Budget Committee, Jim Slattery, Marty Sabo, and Dick Durbin, for their strong support for the Medicaid initiatives in the fiscal year 1991 budget resolution.

Without objection, your complete statements will be in the record in full.

We would like also, without objection, the statement of Chairman Panetta who was unable to join us this morning due to the budget summit that will be inserted into the record.

[The prepared statement of Mr. Panetta follows:]

PREPARED STATEMENT OF HON. LEON E. PANETTA, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, thank you for scheduling these important hearings. These hearings will help us better understand the need to make hospice coverage a mandatory benefit under the Medicaid program. As you know, you and I introduced H.R. 3935 on February 1 of this year, along with 35 of our colleagues. This bill would mandate coverage of hospice care for those individuals covered under Medicaid.

This compassionate and cost-effective service which serves the terminally ill and their families was made an option under Medicaid in legislation passed and enacted in the 99th Congress. At the same time the hospice Medicare benefit was made permanent. More recently, as part of the Omnibus Budget Reconciliation Act of 1989, a 20 percent increase for Medicare hospice reimbursements was enacted. I was proud to have been the sponsor of those pieces of legislation and I am pleased to have this bill to extend the Medicare hospice benefit considered by the subcommittee.

Hospice is the practice of caring for the terminally ill in their homes and communities, in a familiar setting among family and friends. Over the past decade, there has been enormous growth in the hospice movement, with approximately 150 new agencies created every year for the past 3 years. Today, there are over 1,700 hospice programs in operation throughout the country, of which 1,450 are full-service programs. Half are already certified by Medicare, and 200 more are in the process of becoming certified.

Through this innovative means of care and support a team of health care professionals and other specialists strives to make the remainder of a patient's life as comfortable and meaningful as possible by providing Medical and therapeutic attention at home. This is enormously important, not only for the patient, but for their family, as well. In this way, hospice helps people cope with the physical, emotional, and spiritual hardships of terminal illness.

Just as important as the humanitarian contributions of hospice, however, is the fact that hospice programs save money. Hospice allows people to move out of acute care facilities, and into less expensive care arrangements. Now that the need to cut Medicare expenditures is reaching crisis proportions, it is especially important to incorporate hospice into national policies. The Congressional Budget Office has estimated that hospice coverage under Medicare could be cut more than $100 million over 3 years. Medicaid expenditures could be cut as well; Illinois, for example, would save at least $1 million per year if it had such a benefit. The State of California has estimated that, once fully implemented, a Medicaid hospice benefit would save over $2.1 million per year, including $1 million in Federal savings. Other evidence that hospice is cost-effective includes several studies which have shown that it saves 20 to 40 percent over traditional acute care, and the fact that numerous major health insurers have included a hospice benefit without having to increase premiums. To reduce the deficit, therefore, the development and utilization of community-based forms of care is crucial.

Mr. Chairman, when the legislation making hospice an option under Medicaid was first introduced, it was with the aim of making this form of care for the terminally ill available to those with low incomes and their families. While the Medicare benefit makes hospice available to the elderly and disabled, who represent a large proportion of those who could benefit from hospice, Medicaid beneficiaries, who are indigent, disabled, or both, still do not have need access to the same services.

Unfortunately, the group without hospice coverage includes a large number of AIDS patients, and will include many more as this tragic disease spreads. As you know, AIDS is one of the greatest epidemics to strike this country. The severity of the problem is illustrated by some grim statistics: As of February 6, 1989, there were 85,590 reported AIDS cases and 48,957 deaths as a result of the disease. Projections by the Public Health Service and the Centers for Disease Control predict the death toll will rise to 180,000, with over 50,000 deaths occurring in 1991 alone.

Clearly, there is a pressing need to care for the rapidly growing number of persons who are dying of AIDS, and this must be done in the most cost-effective and compassionate manner possible. Hospice, with its combination of in-patient and outpatient care, provides the most appropriate means of providing for this group. Last year, hospices cared for 25 percent of all those who died of AIDS. Clearly, it is a highly desirable service.

The large and rapidly-growing number of intravenous drug abusers among AIDS patients is a further incentive to expand access to hospice. These individuals are often homeless or come from unstable living situations which do not allow for appropriate care at home without outside assistance. Hospice is already the best possible care for this group. Expanding the hospice Medicaid benefit through this legislation will enhance many more AIDS patients to receive the care they need in hospice programs. Otherwise, they will be forced into expensive acute care settings or, worse, into the streets.

Because of the AIDS epidemic, the cost savings of hospice will be even more significant. Here, we may take a lesson from local efforts to cope with the disease. The average cost of caring for an AIDS patient during the last year of life is about $66,000 in Atlanta, and $120,000 in New York City. Neither of these cities makes extensive use of hospice programs. In San Francisco, however, care for the same patient would cost only $25,000 because of advanced AIDS programs including an extensive network of hospice services. Hospice must be expanded to keep costs down as an increasing number of indigent patients seek treatment for the disease.

Mr. Chairman, so far, 18 States, including New York, Michigan, Florida, Illinois, Texas, and North Carolina, have created a Medicaid hospice benefit since the enactment of the option. Although it is encouraging that several other States are also taking steps to create such a benefit, I believe, along with the other cosponsors of this bill, that the current need is great enough to warrant making the hospice Medicaid benefit mandatory. This makes hospice services available sooner to Medicaid beneficiaries throughout the country.

The bill would become effective for calendar quarters beginning on or after July 1, 1991. If necessary, States would be allowed additional time to enact any required legislation. I urge my colleagues to give their approval to this measure to provide access to hospice coverage for those who need it most while saving taxpayer and government funds in the process.

Thank you, Mr. Chairman.

Mr. WAXMAN. Because of the large number of witnesses, I would like to ask each of you, if you would, to limit your oral presentation to no more than 5 minutes.

We are delighted to have you with us. We have read your introduction for each of you, and just highlight the very important role that each of you has played in the Medicaid area, and, of course, that does not go into all of the other areas in which you have been congressional leaders.

Mr. Swift, why don't we start with you.

STATEMENTS OF HON. AL SWIFT (WASHINGTON); JIM SLATTERY (KANSAS); JIM COOPER (TENNESSEE); GEORGE MILLER (CALIFORNIA); TED WEISS (NEW YORK); MARTIN OLAV SABO (MINNESOTA); BARBARA KENNELLY (CONNECTICUT); AND RICHARD J. DURBIN (ILLINOIS), ALL REPRESENTATIVES IN CONGRESS

Mr. SWIFT. Thank you very much, Mr. Chairman. I would like to comment that I think Jim Scheuer and I are the only two on the panel old enough to remember a "Cavalcade of Stars", which only proves that Mr. Wyden is a lot older than he looks.

Mr. WAXMAN. That was a radio show, wasn't it?

Mr. SWIFT. A long time ago.

As I told Dick Durbin, the only time I really distrust any of my colleagues is when they begin by saying "I will be brief," so rather than promise, I will simply try.

I am here to testify on H.R. 5057, which was introduced by Sandy Levin, which deals with the question of living wills.

Living wills are something that I think need to have a Federal focus to expand the awareness and to encourage the use thereof.

They deal with the very difficult question of who decides what to do when medical situations appear hopeless. They answer the question by saying, "You do."

As I talk to seniors, people who have arrived at a time in life when they seem to be able to recognize their own mortality more than probably anyone in the room, including Mr. Scheuer and me, can yet, you find that there tends to be a sharp reduction of the fear of death and a great concern that it will come with no dignity at all.

One of the things, and I certainly don't think living wills are something that only elderly people could use, but it does seem to me that for a person, and particularly for the elderly, to be able to detail the circumstances under which heroic efforts of medical attention are no longer required, is something that makes a great deal of sense for the individual; it relieves from medical professionals, families and others at very difficult times that responsibility, and it is something that I think more Americans should be aware of and should have to determine if that isn't a decision that they would like to make themselves by making out a living will and leaving that for consultation if dire circumstances come about.

I urge this committee to pass that legislation as quickly as possible.

This one really only puts a focus on it, puts the Federal Government's ability to focus on the issue, still leaves most of the details up to the States.

I think it is a modest, moderate rational approach and I urge it to the committee's attention and I thank the chairman very much for the opportunity to testify.

Mr. WAXMAN. Mr. Slattery.

STATEMENT OF HON. JIM SLATTERY

Mr. SLATTERY. Thank you, Mr. Chairman. It is a pleasure to be here and I, for one, really appreciate, Henry, the work that you have done and the work that this committee has done in the past to advance the cause of health care for poor children in this country. You have been a champion, and this committee has worked hard and I have enjoyed working with you.

So it is a pleasure to be here and testify on H.R. 3932, legislation which I introduced earlier this year, and I will just spend a couple of minutes talking about the minor provisions of it.

This legislation would require States to phase in Medicaid eligibility for all children under the age of 18 with family incomes less than the Federal poverty standard beginning in 1991. The mandate would begin with eligible children born after September 30, 1983.

Current law does require States to provide Medicaid eligibility to children under age 6 whose family incomes are less than 133 percent of the Federal poverty standard. However, for children ages 6 through 17, the Federal Government requires States to provide Medicaid eligibility only if the family's income is less than the State's welfare eligibility standard, which of course in many States is often substantially lower than the Federal poverty line.

In addition, this legislation would give the States the option to extend Medicaid eligibility to children under age 6 with incomes greater than 133 percent of the Federal poverty standard and not more than 185 percent, and it would permit the State to extend the period of Medicaid transition coverage, the number of months during which the State would pay for Medicaid coverage for an individual who has left welfare to become employed from 12 months to 24 months, and it would also prohibit States from imposing durational time limits on medically necessary inpatient care for Medicaid eligible children under age 18 in disproportionate share hospitals. Current law prohibits such limits on inpatient care for infants in disproportionate share hospitals.

This legislation will also give the States the option to extend Medicaid eligibility to foster care children whose incomes are above the State welfare eligibility standard, but below the Federal poverty level.

And the last point I would make about the legislation in terms of its substance is that it requires the States with restrictive Medicaid eligibility standards for SSI recipients to extend Medicaid eligibility to disabled children under age 18 who qualify for SSI. According to the U.S. Department of Health and Human Services in a report earlier this year, total spending on health care among Americans has skyrocketed, rising from 6 percent of GNP in 1965 to 11 percent in 1988.

The United States spent a record $540 billion on health care in 1988, and the data coming in now indicates that we better brace ourselves for the last year's number, which will probably be $600 billion for 1989. But despite this massive expenditure, the health of millions of disadvantaged children is eroding. They are clearly the victims of a health care system which unevenly distributes health care and health insurance, and which shortchanges low and moderate income children.

Children are securing a smaller and smaller portion of Medicaid's resources with each succeeding year. Although children account for half of all those receiving Medicaid today, they get only one-fifth of Medicaid expenditures, while the elderly comprise 16 percent of the Medicaid population and use 39 percent of its resources.

According to one study, the elderly, once the poorest group of Americans, saw their poverty rate decline from 12.5 percent to 12.4 percent during the period 1966 to 1986, but over this same period, children became the new poor with almost one quarter of all children 5 years of age or younger now living in poverty.

To bring this disparity home to health care, Medicaid pays physicians less than half the amount Medicare allows for a typical office visit in almost 25 percent of the States. It is an unfortunate fact that millions of American families and children are forced to go without necessary care because they can not afford it.

Buying medical care has become so expensive that access to health insurance has become a crucial determinant of access to health care. Among low-income children, those who are uninsured receive only about one half as much medical care as those with health insurance.

Mr. Chairman, many studies suggest that skimping on Medicaid for children is shortsighted public policy. The savings that Medicaid must realize later turn out to be cash flow nightmares as the cost of care skyrockets for even more chronic and debilitating conditions. Medicaid for children may be among our best investments in poverty prevention for adults.

Mr. Chairman, to put it simply, America needs to get serious about Medicaid and health care for poor children. We cannot forget that for a poor child, Medicaid is often the difference between seeing a doctor regularly and ending up in the emergency room later and sicker. Medicaid means not having to choose between medicine for a child and food for the table.

In closing, Mr. Chairman, I would just point out that Senator Bentsen has introduced companion legislation in the Senate, as you indicated in your opening remarks, the Budget Committee did make $50 million this year, $2.25 billion over the next 5 years to pay for this legislation, and I would just point out that this is a pittance when compared to some of the other expenditures that this government makes, and as far as I am concerned, this is one of the soundest investments we can make in the future of our country.

If there is anything that we can morally justify borrowing money for, it is to provide health care for the children that we expect to pay the bills that we are handing to them. So I would strongly urge this committee on a bipartisan basis to work together to implement one of the campaign promises that President Bush made in the last campaign.

I thank the chairman for his interest.

[The prepared statement of Mr. Slattery follows:]

Prepared Statement of Hon. Jim Slattery, a Representative in Congress From the State of Kansas

Mr. Chairman, I am pleased to be here today to speak in support of H.R. 3932, the Medicaid Child Health Amendments of 1990, which I introduced earlier this year. I know that you have been a champion for childrens' health issues and for the Medicaid program. I appreciate your support and commitment to this bill and this opportunity to comment on the importance and urgency of this legislation.

H.R. 3932 would address a very urgent and important need in our country today by providing basic health care for our nation's poor children. In particular, H.R. 3932 would:

(1) Require States to phase in Medicaid eligibility for all children under age 18 with family incomes less than the Federal poverty standard beginning in 1991. The mandate would begin with eligible children born after September 30, 1983. Current law does require States to provide Medicaid eligibility to children under age 6 whose family incomes are less than 133 percent of the Federal poverty standard. However, for children ages 6 through 17, the Federal Government requires States to provide Medicaid eligibility only if the family's income is less than the State's welfare eligibility standard, which often is substantially below the Federal poverty level.

(2) Give States the option to extend Medicaid eligibility to children under age 6 with incomes greater than 133 percent of the Federal poverty standard and not more than 185 percent.

(3) Require States to provide for enrollment—the receipt and initial processing of Medicaid applications—in locations other than the welfare office such as hospitals and clinics.

(4) Permit the State to extend the period of "Medicaid transition coverage"—the number of months during which the State will pay for Medicaid coverage for an individual who has left welfare to become employed—from 12 to 24 months.

(5) Prohibit States from imposing durational time limits on medically necessary inpatient care for Medicaid eligible children under age 18 in disproportionate share hospitals. Current law prohibits such limits on inpatient care for infants in disproportionate share hospitals.

(6) Require States to provide outlier payment adjustments for exceptionally high cost or long stay cases of Medicaid eligible children under age 18 receiving inpatient care in disproportionate share hospitals.

(7) Require States to continue Medicaid assistance for children under age 18 who are determined to be no longer eligible until the State can determine that the child is not eligible under another provision of Medicaid law. Beforepassage of this bill, I would amend this provision to ensure that Medicaid coverage for infants remains continuous until age 1 without the requirement of a separate application. Chairman Waxman, I know that you also support such an amendment.

(8) Give States the option to extend Medicaid eligibility to foster care children whose incomes are above the State welfare eligibility standard but below the Federal poverty level.

(9) Require States with restrictive Medicaid eligibility standards for SSI recipients to extend Medicaid eligibility to disabled children under age 18 who qualify for SSI.

According to the U.S. Department of Health and Human Services, in a report issued earlier this year, total spending on health care among Americans has skyrocketed, rising from 6 percent of the Gross National Product [GNP] in 1965 to 11 percent of the much larger 1988 GNP.

The United States spent a record $540 billion on health care in 1988 and when the data becomes available, we can expect to see that we will have spent over $600 billion on health care in 1989.

But despite this massive expenditure, the health of millions of disadvantaged American children is eroding. They are the victims of a health care system which unevenly distributes health care and health insurance and which shortchanges low and moderate income children.

Children are securing a smaller and smaller portion of Medicaid's resources with each succeeding year. Although children account for half of all those receiving Medicaid today, they get only one-fifth of Medicaid expenditures, while the elderly comprise 16 percent of the Medicaid population and use 39 percent of its resources.

According to one study, the elderly, once the poorest group of Americans, saw their poverty rate decline from 28.5 to 12.4 percent from 1966 to 1986. But, over this same period, children became the "new poor," with almost one- quarter (23 percent) of all children 5 years or younger now living in poverty.

To bring this disparity home to health care, Medicaid pays physicians less than half the amount Medicare allows for a typical office visit in almost one-quarter (23 percent) of the States.

It is an unfortunate fact that millions of American families and children are forced to go without necessary care because they cannot afford it. Many—especially lower income working families and unemployed families—are not covered by either private oe public insurance.

Buying medical care has become so expensive that access to health insurance has become a crucial determinant of access to health care: among low-income children, those who are uninsured receive only about one-half as much medical care as those with health insurance. Yet both our private and public health insurance systems have widening cracks. Between 1982 and 1985, the number of uninsured Americans grew by 15 percent (from 30.3 to 34.8 million), and the number of uninsured children grew by 16 percent (from 9.6 to 11.1 million).

Health care provided to children, especially preventive health measures taken throughout a child's life, is immensely effective, paying off in improved health as well as in financial savings for government and society. Children who receive comprehensive pediatric care, including preventative services, have been shown to have annual health care costs 10 to 25 percent less than children who do not.

Many studies suggest that skimping on Medicaid for children is shortsighted public policy.

The "savings" that Medicaid must realize later turn out to be cash flow nightmares, as the cost of care skyrockets for even more chronic and debilitating conditions. Medicaid coverage for children may be among our best investments in poverty prevention for adults.

Mr. Chairman, to put it simply, America needs to get serious about Medicaid. If it is to fulfill its promise to the poor children of this country, Medicaid needs to assure actual and ample access to necessary health care services through adequate coverage for those children eligible for Medicaid.

We cannot forget that for a poor child, Medicaid is often the difference between seeing a doctor regularly and ending up in the emergency room, later and sicker. Medicaid means not having to choose between medicine for a child and food for the table.

The time is long overdue for the Nation that leads the world in medical technology to ensure the provision of basic health care for poor children and families. I believe this bill will help to deliver this basic care to those children most in need. I strongly encourage this committee and my colleagues to support it.

Mr. WAXMAN. Thank you, Mr. Slattery.

STATEMENT OF HON. JIM COOPER

Mr. COOPER. I would like to join my colleagues in thanking the chair and members of this subcommittee for their outstanding leadership on all health care issues.

My particular concern today is a bill that would protect State Medicaid budgets from an unwarranted intrusion by the Federal Government.

My bill, H.R. 4181, would stop efforts by the Health Care Financing Administration to place restrictions on voluntary contributions and provide our specific taxes on State Medicaid programs. I know that in my State of Tennessee as well as many other States, HCFA's restrictions would severely diminish the quality of medical care available to thousands of poor people.

HCFA's motivation in introducing their new rule is very simple. They wanted to avoid matching grants to the States. On the surface, there seems to be no easier way to save money, but I believe a close examination of this policy shows that it is not only harsh on State budgets, which are increasingly under strain due to growing health care costs, but it is also shortsighted.

Sure enough, HCFA may be able to wring out savings in the first year, but those savings will come directly from reduced medical services to needy Medicaid recipients and payments to providers. You cut funding without any other changes to the system, people will simply suffer.

Furthermore, States will eventually have to find other sources of revenue, probably through higher general taxes, and the savings that HCFA is counting on will vanish.

I do agree with HCFA's desire to save money—but I want to find real savings. In order to get these savings, we need to have the courage to take a hard look at the system and implement real reforms—reforms which would affect providers, patients, and the system as a whole. States simply cannot tolerate indiscriminate cuts in their barebones Medicaid programs. Refusing to match an entire category of State money is not just bad public policy, but produces no real savings.

My bill essentially leaves State finance matters to the States, as they should be, and contains the exact same provisions we endorsed last year as a committee and as a Congress.

In conference committee last year, a 1-year HCFA moratorium was finally substituted for our bill. But this is too serious a problem to be solved with moratoria every year. The time has come to help ensure that the States will continue to have the flexibility to raise funds that they need to have.

I thank the chair and yield back the balance of my time.

Mr. WAXMAN. Thank you very much, Mr. Cooper. I appreciate that statement.

I invite colleagues on the panel if they have a quick question of any of our witnesses, rather than wait until all of them have completed their statements, because I know they all have busy schedules, and unless there are no questions, Mr. Cooper, you are welcome to stay, but we understand you may have to leave, and the same for Mr. Slattery.

Mr. Miller.

STATEMENT OF HON. GEORGE MILLER

Mr. MILLER. Thank you, Mr. Chairman, and I wanted to concur in the statements made by my colleagues. I think they are all addressing very important aspects of the Medicaid program and the work you do in your subcommittee in an effort to expand the coverage to people in need.

I would just quickly like to confine my remarks to address what I think is a major concern, and that is the dire shortage of drug treatment faced by addicted women who are pregnant or postpartum.

In my prepared statement, I go through two case histories of two women who had a series of tragic events in their lives with respect to newborn babies and the loss of children, the loss almost of their individual lives, but both of whom have now become success stories. The thing that they have in common is the fact that they were able to receive comprehensive drug treatment during pregnancy. But they are clearly, as you know, the exception to the rule, because nationally, less than 11 percent of women who are pregnant and in need of drug treatment are receiving care. And there are a number of reasons for that, but within the jurisdiction of this committee, I think it is necessary to address the uncertainties and the ambiguities of the Health Care Financing Administration and their requirements that discourage the creation of drug treatment facilities for pregnant women.

Many pregnant addicted women are waiting for residential treatment services and other kinds of support because service planners cannot count on Medicaid as the sustainable funding base. Resourceful treatment providers have attempted to work every angle under the Medicaid statute, but none has proven reliable.

Most residential substance abuse programs for women are unable to receive Medicaid coverage because they are not considered hospitals or psychiatric hospitals. Several States are attempting to provide some partial hospitalization by pressing the limits of the HCFA definition of rehabilitative services, but this is generally not allowed.

Methadone maintenance and hospital detoxification are clearly covered by Medicaid, but these therapies are simply not appropriate for the addictions of alcohol and cocaine, the drugs most frequently used by the majority of female substance abusers.

Services designed to address pregnancy complicating conditions are discontinued 60 to 90 days after the last day of pregnancy, but most women require more time to change the addictive patterns that they have taken years to acquire.

The most shortsighted provision, however, of the current Medicaid law is the "institute for mental disease" exclusion. When HCFA determines that a residential drug treatment program is an institute for mental disease, residents become ineligible not only for drug treatment, but also for all Medicaid coverage concluding prenatal care.

While facilities with fewer than 17 beds are exempt from the pernicious IMD exclusions, these patients are not covered for room and board fees. Added to the problems of economy of scale, such funding restrictions make very small facilities an inviable option in most places.

Our witnesses spoke about these problems, those representing treatment programs and those aspiring to start treatment programs, and yet we find that they simply are not able to get around these complications in the HCFA law. We find that we are now spending millions of dollars on crisis health care services for addicted women and their infants, because pregnant women lack treatment early on during that pregnancy.

Preventing the damage and the disruption would be cheaper by far. The Inspector General of HHS has estimated we are currently spending about a billion and a half dollars on foster care and hospital services for those children already born cocaine exposed. And yet we know that we can provide this kind of treatment for women for about $60 million a year.

And I think while we are all mindful of the budget concerns and the constraints that we have on us, this is clearly a tradeoff that must be made, and it clearly is something that must be done in the name of drug treatment and drug prevention.

We are told time and again by witnesses that pregnancy presents a very unusual opportunity to deal with the addiction of women and the habits, whether it is cessation of smoking, alcohol, cocaine, what have you, because of the desire to have a healthy outcome of that pregnancy. We are now missing that opportunity.

As a result of missing that opportunity, we are having a growing number of babies born drug exposed or addicted to other substances, and as a result of that, we are having less healthy babies and we are paying billions of dollars unnecessarily to make up for the mistake of not seeing that pregnant woman early on in her pregnancy and providing the kind of comprehensive care that we know leads to successes.

In the program that Mr. Durbin and I visited in Detroit, for the entire city of Detroit there were 26 beds for pregnant women, but some 4,000 women who have inquired or had inquired on their behalf about the possibility of placement in these programs during pregnancy over the years.

That gives you an idea of the gap that needs to be filled, and I would hope that this committee in further considerations of the expansion of Medicaid would also look at those regulations that are proving so cumbersome to those people who are trying to provide drug treatment to pregnant women.

Thank you very much for your time.

[The prepared statement of Mr. Miller follows:]

PREPARED STATEMENT OF HON. GEORGE MILLER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman and Members of the subcommittee, thank you for the opportunity to address your committee. You are already aware of my strong support for several of the present proposals regarding Medicaid expansion, particularly those which further expand eligibility and outreach for pregnant women, infants, and children, and services for people living with AIDS. I will confine my remarks today to another major concern—the dire shortage of drug treatment faced by addicted women who are pregnant or post-partum.

As Chairman of the Select Committee on Children, Youth, and Families, I was made aware of the pressing treatment needs of these women in a series of three hearings on perinatal substance abuse the committee held this past spring. We heard testimony from women recovering from addiction, from treatment providers and advocates, and from scientists conducting research in this area, who described the needs of pregnant women who abuse drugs.

One witness, Kathleen, a white, upper middle class daughter of saloon owners, had been reduced by her heroin addiction to living in cars. Kathleen described her 15-year struggle to find the long-term treatment she so desperately needed. In and out of short-term, hospital-based treatment programs, she became pregnant several times in what she called misguided efforts to change her life. One baby died of SIDS, and another was born with fetal alcohol syndrome. Her other daughter and son had to endure repeated school changes, unmet physical and emotional needs, and constantly broken promises.

Because Kathleen had parents who could care for her children and pay for treatment when she was eventually referred to a private, long-term, residential program, she was able to recover. She has been sober and drug free for 8 years, and is employed today doing outreach and public education for the facility that finally helped her. Her son is in college, her 13-year-old daughter is on the honor roll, and she told us through tears that her daughter with FAS is doing "really very well."

More defiant of the odds and our stereotypes is the recovery of Courtney, a woman who recently completed treatment at the Eleonore Hutzel Recovery Center in Detroit, where the Select Committee recently held a field hearing. Courtney is black, poor, and recovering from crack cocaine addiction. Like many women, she became motivated to stop using drugs when a pregnancy was diagnosed. When she relapsed after coeducational treatment, she agonized and eventually decided to put her first baby up for adoption. After vain attempts to stop using drugs on her own, she abandoned her second infant in the hospital where he was born, convinced that social services would provide him with a better life than she could.

But Courtney has a new baby now. Her son, Anthony, is thriving and lives with his mother at the Recovery Center. This model program is carefully deigned to address the special needs of substance abusing women. It does not turn women away if they are poor, and it includes therapeutic services, daycare, and housing for their infants. Courtney feels that she has acquired the skills and the support she will need to stay straight when she moves away from Hutzel, and she knows she is lucky to have been admitted there.

Almost half of the 9,000 infants delivered at Hutzel Hospital in a recent year were born exposed to illegal drugs, but the Recovery Center has only 26 residential treatment slots. Nationally, less than 11 percent of pregnant women in need of drug treatment are receiving care. A witness from Atlanta told us that half of the indigent pregnant women who presented themselves for drug treatment there are turned away for lack of space.

We heard similar stories of treatment shortages from witnesses from across the country. There is a serious lack of both residential and outpatient drug treatment for pregnant, substance abusing women. As you know, Mr. Chairman, one of the major barriers to the provision of adequate residential care is our failure to include it explicitly under Medicaid coverage.

Uncertainties and ambiguities in Health Care Financing Administration [HCFA] requirements discourage the creation of drug treatment facilities for pregnant women. Many pregnant, addicted women are waiting for residential drug treatment services and other kinds of supports because service planners cannot count on Medicaid as a sustainable funding base.

Resourceful treatment providers have attempted to work every angle under the Medicaid statute, but none has proven reliable:

(1) Most residential substance abuse programs for women are unable to receive Medicaid coverage because they are not considered hospitals or psychiatric hospitals.

(2) Several States are attempting to provide some partial hospitalization by pressing the limits of HCFA's definition of "rehabilitative services," but this is not generally allowed.

(3) Methadone maintenance and hospital detoxification are clearly covered by Medicaid, but these therapies are simply not appropriate for addictions to alcohol and cocaine, the drugs most frequently used by the majority of female substance abusers.

(4) Services designed to address "pregnancy complicating conditions" are discontinued 60–90 days after the last day of pregnancy, but many women require more time to change addictive patterns that took years to acquire.

The most shortsighted provision of current Medicaid law is the "Institute for Mental Disease" [IMD] exclusion. When HCFA determines that residential drug treatment program is an institute for mental diseases, residents become ineligible not only for drug treatment, but also for all Medicaid coverage, including prenatal care!

While facilities with fewer than 17 beds are exempt from the pernicious IMD exclusion, their patients are not covered for room and board fees. Added to problems of economy of scale, such funding restrictions make very small facilities an inviable option in most places.

Our witness who spoke about the drug treatment needs of Indian women said that the biggest impediments to service delivery were the distrust and lack of cooperation between the fields of drug treatment and mental health. Whether this turf battle underlies the exclusion of residential drug treatment programs from Medicaid funding, or whether it has resulted from a counterproductive attempt to save Medicaid dollars, or simply from legislative oversight, we spend increasing millions on crisis health services for addicted women and their infants because pregnant women lack drug treatment.

Preventing damage and disruption would be cheaper by far. The Inspector General of the Department of Health and Human Services recently estimated that the cost for providing hospital and foster care services through age 5 for children already born cocaine-exposed could be $1.5 billion. The Congressional Budget Office estimated that mandated Medicaid residential treatment coverage for pregnant and post-partum women would cost only $60 million per year—the cost of maintaining U.S. troops in Saudi Arabia for 2 days.

We are all mindful of harsh constraints on governmental spending this year. In this fiscal context, I support a compromise first step in the right direction. Offering a Federal match for residential drug treatment coverage as an option for States would cut the estimated cost to the Federal Medicaid program in half. A few States have already begun to address this problem; we must not penalize them for rising to meet the challenge before we do.

Effective drug treatment for pregnant women must be part of a coordinated system of services that enables recovering addicts to become independent economically as well as chemically. No one claims that this kind of care is inexpensive, but few would deny that it is not cost effective.

More important, when treatment works, the savings in human misery for both mother and child are incalculable. A hopeful note was sounded by several researchers at our hearings who provided evidence that pregnancy is a time of unusual motivation to get straight, and a time when family and friends exert pressure to stop using drugs for the sake of the baby.

HCFA is telling State Medicaid directors to expand coverage for drug treatment, but only as previously defined. It is obvious that the statute itself must be changed to fill the existing gap in coverage between outpatient services and hospital-based care. Hospital care is extremely expensive and typically inappropriate for this population.

We cannot afford to wait to help these families. I urge you to address their urgent needs as you craft Medicaid extension legislation. Thank you.

Mr. **Waxman**. Mr. Wyden.

Mr. **Wyden**. Thank you, Mr. Chairman. Just one quick question.

George, you did an excellent job, as always. The qualifications for Medicaid, particularly with kids, just seems bizarre, I call it a crazy quilt, the business of somebody whose wife being guaranteed coverage, but their older brother or sister who is 8 years old not being guaranteed coverage, and there is just no explanation for it.

Is there anything out there that you know of besides budget that is keeping these eligibility considerations the way they are?

Mr. **Miller**. That is what is driving the process, and tragically as we see time and again, very often those considerations that call upon this administration and any administration and the Congress dealing with budget constraints to provide for these exclusions very often leads to more expensive care rather than reducing the expenditures of the government later on.

Mr. **Wyden**. As far as I am concerned, probably the only flaw in the argument is you are being too logical given the——

Mr. **Miller**. That is one of my faults.

Mr. **Wyden**. Mr. Chairman, thanks.

Mr. **Waxman**. Mr. Rowland.

Mr. **Rowland**. Thank you, Mr. Chairman.

I just want to call attention to what George Miller has done over the years. He certainly has focused a lot of attention on these problems some years back when it wasn't a real popular thing to do.

So I just appreciate all that you do, the information that you bring out, and how important it is for us to deal with these problems, and the fact that it does save a lot, not only in monetary terms, but in human suffering, too, to address these problems.

So, George, I am real pleased with what you do.

Mr. MILLER. Thank you, Roy, and thank you for your participation in all that work.

Mr. WAXMAN. Dr. Rowland speaks for all of us.

We thank you very much.

Mr. MILLER. It is exciting to see that Medicaid has drawn this many of our colleagues. You would think this was the Appropriations Committee giving away highways or something. This may be a new day.

I don't mean to insult you guys on Appropriations.

Mr. WAXMAN. Pleased next to hear from Mr. Weiss.

STATEMENT OF HON. TED WEISS

Mr. WEISS. Thank you very much, Mr. Chairman. I do want to commend you and the subcommittee for the outstanding leadership that you have demonstrated in this area.

I would like to focus my testimony today on the quality of care delivered to beneficiaries. As you have indicated, the Government Operations Subcommittee that I have the privilege of chairing is in the midst of reviewing the quality of care in the Medicaid program.

Our investigation is finding that substantial numbers of Medicaid patients are subjected to highly dangerous medical treatment by neglect or incompetent physicians. Although I believe that these physicians represent a very small percentage of our Nation's doctors, poor care provided by them can wreak medical havoc on thousands of patients.

In large urban areas such as New York City, we are identifying patterns of poor care involving physicians who are often educated in Third World Countries, not certified to practice by loose State medical licensing system. These physicians are hired by unscrupulous entrepreneurs to work in shared health facilities, more commonly known as Medicaid mills.

The care provided by the worst Medicaid mills is characterized by a wide range of improper practices, including blatant drug dealing, overutilization of diagnostic tests and the failure to provide even minimal quality of care.

It is not too much to say that in most instances the care provided for them is worse than not having any care at all. Innercity neighborhoods with large Medicaid eligible populations of doctors who are available, most do not provide the full spectrum of care considered to be basic medical practice in the United States. The majority of these physicians lack board certification or hospital affiliations, including more than half of those who provide care to pregnant women.

Compounding the problem is the inability or unwillingness of Federal or State Medicaid authorities to remove dangerous doctors from the Medicaid system, even after their maltreatment of Medicaid patients has been identified.

The Federal Government need not condone this treatment by dangerous physicians. We just should close the loopholes that allow incompetent physicians to treat Medicaid patients, to prevent truly incompetent physicians from treating Medicaid patients.

The proposed legislation will help State government keep tabs on incompetent doctors by requiring that Medicaid physicians have unique identifying numbers for billing purposes. Under this provision, the identifying numbers of the physicians who actually treat Medicaid patients must be included in the billing, thus preventing incompetent physicians from using large health care firms to disguise their participation in Medicaid.

The bill also requires foreign medical school graduates to pass a certification exam already required for participation in the Medicare program in order to be eligible for Medicaid reimbursements.

To prevent the problem of unqualified doctors providing specialized treatment to providing specialized treatment to patients, the bill would require that facilities requiring pediatric and obstetrical services either be certified or hospital affiliated in these specialties or have a consulting arrangement with a physician who is certified or hospital affiliated.

The legislation would also require State governments to conduct quality of care reviews of high volume physicians or health care plans.

Finally, my proposal would require all State health care agencies to report any adverse findings involving physicians in the Medicaid program to the Federal Government even when no formal action has been taken against the physician.

Mr. Chairman, thank you again for holding this hearing and thanks to your staff for their cooperation and advice. I look forward to working with you in the development of legislation to improve quality of care in the Medicaid program.

I am submitting a copy of my statement and legislation for the record.

Mr. WAXMAN. Thank you very much, Mr. Weiss, for that statement and for your legislation. It has given us a new perspective on Medicaid being involved and trying to correct these abuses, and I think we will want to look at it very carefully and consider it very carefully.

Mr. WEISS. Thank you.

[The prepared statement of Mr. Weiss follows:]

PREPARED STATEMENT OF HON. TED WEISS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Medicaid is a vast program with many complications and problems in need of solutions. Among the maladies afflicting Medicaid are fraud, inflationary medical costs, and the increasing inability of State Governments to fund their share of the basic services required by the needy and infirm. These major problems merit the attention of this panel.

Without in any way minimizing the varied concerns of my distinguished colleagues, health care providers, and patients, I will focus my testimony today on the quality of care delivered to Medicaid beneficiaries. The Government Operations Subcommittee that I have the privilege to chair is in the midst of a review of quality of care in the Medicare program. We conducted an initial hearing in my home State of New York, whose problems are similar to those of other States with large urban populations.

Our investigation is finding that substantial numbers of Medicare patients are subjected to highly dangerous medical treatment by negligent or incompetent physicians. Although I believe these physicians represent a very small percentage of our Nation's doctors, in a State like New York—where only 15 percent of the licensed physicians treat Medicaid patients—the poor care provided by a few doctors can wreak medical havoc on thousands of patients.

In large urban areas such as New York City, we have identified patterns of poor care involving physicians who are often educated in Third World Countries and are certified to practice by a loose State medical licensing system. These physicians are hired by unscrupulous entrepreneurs to work in Shared Health Facilities, more commonly known as Medicaid mills. The care provided by the worst Medicaid mills is characterized by a wide range of improper practices, including blatant drug dealing, overutilization of diagnostic tests, and the failure to provide even minimal quality of care.

In New York City, it is estimated that there is a shortage of 500 physicians in the inner city neighborhoods with large Medicaid-eligible populations. Of the doctors who are available, most do not provide the full spectrum of care considered to be basic medical practice in the United States. The majority of these physicians lack board certification or hospital affiliations, including more than half of those who provide care to pregnant women.

It is astonishing that some of these physicians are licensed and allowed into the Medicaid program in the first place. But compounding the problem is the inability or unwillingness of Federal or State Medicaid authorities to remove dangerous doctors from the Medicaid system, even after their maltreatment of Medicaid patients has been identified.

Financial fraud is treated more seriously by State Medicaid agencies than negligent medical care. More resources are spent on fraud investigations than quality of care reviews. Typically, physicians excluded from the Medicaid program or delicensed by State boards are removed because they committed fraud. Doctors who practice poor quality of care are rarely disciplined with more than a slap on the wrist.

Our review of all Medicaid physicians referred to the New York medical licensing authority for disciplinary action in 1987 and 1988 found that the penalties recommended by the State Department of Health had been dismissed or lessened in 40 percent of the cases. Most of these cases involved fraud. The most egregious quality of care cases investigated by the State were not referred for discipline at all.

We also found that, of the few doctors who are excluded from the Medicaid program, most continue to practice medicine and eventually return to the program after the exclusionay period.

The Federal Government need not condone the lenient treatment given the dangerous physicians. We should close the loopholes that allow incompetent physicians to treat Medicaid patients. Today I am proposing remedial steps that the Congress can adopt to prevent truly incompetent and negligent physicians from treating Medicaid patients.

My proposed legislation will help State governments keep tabs on incompetent doctors by requiring that Medicaid physicians have unique identifying numbers for billing purposes. Under this provision, the identifying numbers of the physicians who actually treat Medicaid patients must be included in the billing, thus preventing incompetent physicians from using large health care firms to disguise their participation in Medicaid.

The bill also requires foreign medical school graduates to pass a certification exam already required for participation in the Medicare program in order to be eligible for Medicaid reimbursements.

To prevent the problem of unqualified doctors providing specialized treatment to patients, the bill would require that physicians providing pediatric and obstetrical services either be certified or hospital-affiliated in these specialties, or have a consulting arrangement with a physician who is certified or hospital-affiliated.

The legislation would also require State governments to conduct quality of care reviews of high-volume physicians or health care plans.

Finally, my proposal would require all State health care agencies to report all adverse findings involving physicians in the Medicaid program to the Federal Government, even when no formal action has been taken against the physician.

These protections for Medical patients will not create additional costs for the program; in fact, they should save money by keeping out of the program physicians who are prone to overutilization. The intent of my proposed bill is to ensure that Medicaid patients receive the best available care, and that the program no longer be susceptible to rip-off artists and unqualified physicians.

Mr. Chairman, thank you for holding this hearing, and thanks to your staff for their cooperation and advice. I look forward to working with you in the development of legislation to improve quality of care in the Medicare program. I am submitting a copy of my statement and legislation for the record.

Mr. WAXMAN. Any questions?

If not, we thank you very much for being with us, and we would like to next hear from Mr. Sabo.

STATEMENT OF HON. MARTIN OLAV SABO

Mr. SABO. Thank you, Mr. Chairman and members of the committee. I appreciate this opportunity to appear to thank the committee for including language in last year's reconciliation bill relating to personal care attendants and to ask you to do so again.

The Health Care Financing Administration has interpreted Federal law in a manner which restricts the delivery of personal care services to an individual's home, thereby making the home of a disabled person as confining as an institution. Individuals receiving this care are not allowed to take a job, do volunteer work, go shopping or even go to a church or synagogue.

If a Medicaid plan calls for personal care services, it should not matter whether these services are delivered in the home, workplace, school or place of worship. It would in fact be better if people who can work were allowed to do so. They might even be able to earn enough money to get off Medicaid.

Many disabled persons want to work, and some are able to find employment that uses their talents, yet accommodates their disability.

Many of the disabled in Minnesota would fit into this category. I know one individual in particular who has founded and now directs a social service agency which provides assistance and counseling to over 600 disabled persons each year. She requires personal care services, whether or not she works.

The legislation we have introduced specifically allows Medicaid reimbursement of personal care services provided in any setting except a hospital, skilled nursing facility, or intermediate care facility. The services would have to be prescribed by a physician, provided by a qualified individual, and supervised by a registered nurse.

In my judgment, this bill would not increase Medicaid costs. The level of personal care is determined for each individual by a physician based on the individual's need, not upon where the service will be delivered.

If the personal care plan calls for a disabled person for 6 hours of care per day, there is no reason why those services should not be delivered. The bill allows people who are receiving these services to leave their home. It implements what Congress originally intended, that personal care services allow people to remain part of their community.

Thank you.

Mr. WAXMAN. Thank you, Mr. Sabo.

[The prepared statement of Mr. Sabo follows:]

PREPARED STATEMENT OF HON. MARTIN OLAV SABO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MINNESOTA

Thank you, Mr. Chairman, for giving me this opportunity to appear before your committee today. I am here to seek your support for legislation I have introduced which addresses a problem disabled people are experiencing with the Medicaid Personal-Care Services program.

In the past, Congress has recognized the importance of programs that allow disabled individuals to remain in their homes, rather than be institutionalized. Personal-care attendants are trained individuals who provide living and medical assistance to severely disabled persons in order to help them remain in their homes and communities. Attendants assist persons of all ages, including many children.

Because nursing homes can be very costly and many individuals would prefer to remain at home, Congress has supported programs that allow people to remain independent. That was the intent of the Medicaid Personal-Care Services program.

Congress established the program because we wanted disabled individuals to share in their communities' events and activities, to interact with others, to vote, to work and pay taxes, where that was possible. We realized that disabled persons who were confined to their homes were being deprived of the opportunity to participate fully in the life of their communities. Just as important, the rest of us were being deprived of the contributions they could make to our society.

The Health Care Financing Administration has interpreted Federal law in a manner which restricts the delivery of personal-care services to an individual's home, thereby making the home as confining as an institution. Individuals receiving this care are not allowed to take a job, do volunteer work, go shopping, or even go to a church or synagogue.

If a Medicaid plan calls for personal-care services, it should not matter whether these services are delivered in the home, workplace, school, or place of worship. It would, in fact, be better if people who can work were allowed to do so. They might even be able to earn enough money to get off Medicaid.

Many disabled persons want to work, and some are able to find employment that uses their talents, yet accommodates their disability. Many of the disabled in Minnesota would fit into this category. I know of one individual, in particular, who has founded, and now directs a social service agency which provides assistance and counseling to over 600 disabled persons each year. She requires personal-care services, whether or not she works.

I have introduced legislation that addresses this problem. My bill specifically allows Medicaid reimbursement of personal-care services provided in any setting except a hospital, skilled-nursing facility, or intermediate-care facility. The services would have to be prescribed by a physician, provided by a qualified individual, and supervised by a registered nurse.

My bill does not increase Medicaid costs. The level of personal care is determined for each individual, by a physician based on the individual's need, not upon where the service will be delivered. If the personal care plan for a disabled person calls for 6 hours of care per day, there is no reason those services should not be delivered.

My bill allows people who are already receiving these services to temporarily leave their homes. It implements what Congress originally intended, that personal-care services allow people to remain part of their communities.

Earlier this year we passed, and the President signed, the Americans With Disabilities Act. We enacted this law to ensure that persons with disabilities are treated fairly and not denied the opportunity to reach their maximum potential. In this law we require the private sector to provide opportunities for the disabled. At the same time, one of our own Federal agencies is acting in a manner that reduces opportunities for the disabled. Limiting the disabled's access to the outside world runs contrary to the law we passed last spring. It also runs contrary to our original efforts in allowing reimbursement for personal-care services. My legislation clarifies Congress's intent about personal-care services for Medicaid recipients and allows disabled individuals to try to reach their maximum potential. I ask your support for my bill. Thank you for your time.

Mr. WAXMAN. So what you are saying is that HCFA is being too restrictive when they say that personal care services can only be in the home itself.

Mr. SABO. And no place else. And we have tried over the years to get them to change their ruling without success. Our judgment has been they could change it by rule, but to no avail.

Mr. WAXMAN. But they said we have legislative responsibility to carry it out.

Mr. SABO. In your committee last year in reconciliation had a provision which would have changed the provisions. In your judgment, it should not involve any additional costs, and if any, a minimal amount.

Mr. WAXMAN. Mr. Scheuer.

Mr. SCHEUER. What rationale do they give for opposing this? It seems to obviously be common sense on its face.

Mr. SABO. We have tried, there have been hearings, we have submitted testimony, we have badgered to no avail.

Mr. SCHEUER. What do they say? What is their objection based on?

Mr. SABO. I can't speak for them.

Mr. WAXMAN. HCFA will be here this afternoon. Perhaps we can ask them their views on this.

Thank you very much.

Mr. SABO. Thank you.

Mr. WAXMAN. We would like to now hear from Mrs. Kennelly.

STATEMENT OF HON. BARBARA B. KENNELLY

Mrs. KENNELLY. I want to thank Congressman Scheuer for his support and for describing my proposal so that I can immediately begin, Mr. Chairman, addressing some of the concerns that you raised in your letter to me.

I know that you are very much afraid that this will establish a new category of Medicaid eligibility. My full testimony shows how this really allows Medicaid to continue as a real entitlement, and also I think we even help protect against further erosion in the Medicaid program.

I know that you are worried that the enactment of these waivers would result in Medicaid being used to protect assets and to finance the transfer of wealth. I do not think so.

I think it is sound public policy to encourage those with the financial means to do so, to anticipate their future days and to take appropriate steps to plan for them.

At the same time, I think scarce public dollars should be used for the poor that really need them. In this instance, I do not believe that Medicaid is being asked to finance the transfer of wealth.

Further, Mr. Chairman, this proposal is not a permanent restructuring of the Medicaid program, but rather a test of the extent to which private insurance can help solve the long-term financing problem. This is critical as all proposals currently before Congress that envision a role for private supplemental medical insurance.

This leads to your next concern, which is whether this project is really a demonstration or an irrevocable decision on long-term care policy. You are correct in noting that these individuals who enroll during the demonstration would receive a lasting promise of asset protection. Would you have it any way otherwise, Mr. Chairman?

I have not hesitated in saying, and I know you agree, that private insurance must be guaranteed renewable. I understand that you are concerned that taken together, these nine States contain 35 percent of the national elderly, and that perhaps given the lasting nature of the proposals of these demonstrations and the percentage of the elderly population covered, that enactment of this proposal would represent an irrevocable decision on long-term care policy.

I would like to suggest a solution, and maybe this will help us come together on our many divisions. It would be possible to limit participation in each of the States to greater of 50,000 people or 10 percent of the elderly population.

But let me make one point clear, Mr. Chairman. Connecticut wants to be part of this demonstration. My constituents are clamoring for this partnership. Virtually every analysis of these projects including, I am told, soon to be released GAO report, lists Connecticut as a project for the best potential for success.

Finally, you raise the issue of insurance standards. I know this is an issue that this committee and your subcommittee have spent a great deal of time on and are very concerned about.

Let me assure you that this is an issue that has been discussed at great length in each State. Each of the nine States have long-term care insurance standards which exceed those recommended in the National Association of Insurance Commissioners.

One of the purposes of the pilot is to help States better understand just what the regulatory problems are so that appropriate regulatory solutions can be developed. And since you and I are in agreement, if this proposal is to be enacted, it has to be designed to be a true demonstration program.

Let me suggest that comprehensive Federal standards that override States do not belong in such a demonstration. Perhaps a more workable situation would be a situation which includes language that requires that standards at least as strict as those to be reviewed by the subcommittee remain in effect for the duration of the waiver for these demonstration projects.

In this way the subcommittee would be assured that there are strict standards in place while State legislators would be free to strengthen those standards, not weaken them.

Let me conclude, but let me just add another name to our many names that have tried to work these problems out. Dr. Kevin Mahoney, the Connecticut project director, has both the technical and political background, as well as ties to the foundation, to work out any further need for information, and I really hope that we can use him as a resource.

Thank you, Mr. Chairman. And I really, really thank you for your patience in this situation.

Mr. WAXMAN. Thank you very much, Mrs. Kennelly, for trying to be sensitive to these concerns that have been raised and constructive, and looking for ways to resolve these differences.

I know we are going to have a panel and a subsequent hearing on the Medicaid proposal to look at this pilot project in more detail, and we certainly want to work with you to see what we can do.

Mrs. KENNELLY. Thank you.

[The prepared statement of Mrs. Kennelly follows:]

PREPARED STATEMENT OF HON. BARBARA B. KENNELLY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CONNECTICUT

Thank you, Chairman Waxman for your letter inviting me to testify before you today and outlining several questions and concerns you would like addressed regarding my bill, H.R. 2499, which would provide the Medicaid waivers necessary for up to 10 States to conduct their Robert Wood Johnson funded Long-Term Care Demonstrations.

While this is the first public hearing the subcommittee has held on this issue, there have been ongoing discussions between members, staff, States and insurance companies for over a year now.

Therefore, Mr. Chairman, with your permission, I would like to briefly summarize the Robert Wood Johnson Demonstration Project and then use my time to discuss the questions you outlined. In lieu of the length and breadth of your concerns, I am afraid that I may exceed my 5 minutes and would ask your indulgence. I ask that my complete statement be placed in the record. I think this information may be useful to the subcommittee as it prepares for its hearing later in the week when I understand you will hear from a panel of witnesses on this project.

As you know, my legislation, H.R. 2499, would provide Medicaid waivers for those eight States with Robert Wood Johnson Foundation Grants to demonstrate innovative approaches to long-term health care. These States include: California, Connecticut, Indiana, Massachusetts, New Jersey, New York, Oregon, and Wisconsin. The ninth State, Illinois, is also working on innovative financing for long-term care using primarily State funding.

The State of Connecticut has been a leader in developing a public/private partnership approach for financing long term care. The Office of Policy and Management working with the Governor's Task Force on Long Term Care has developed a model which has won the approval of consumers, insurers, representatives of the State AARP and providers. The enabling legislation for this program passed both houses of our General Assembly unanimously after extensive public hearings.

Each of the States is pursuing a somewhat different approach. In Connecticut, individuals would be encouraged to plan for their long-term care insurance commensurate with their assets, or more precisely, in line with those assets they wish to protect. If and when an individual exhausts his or her insurance and applied for Medicaid, each dollar that the insurance policy has paid out in accord with State guidelines will be subtracted from the assets Medicaid considers in determining eligibility. In other words, coverage of long-term care expenses by private insurance would count as asset spend down for the purpose of Medicaid eligibility. Individuals could retain control of assets equal to the amount of insurance paid while income would still be applied toward the cost of care.

That, in a nutshell, is the general program. Now, Mr. Chairman I would like to take the opportunity to address some of the questions you raised about the program in your invitation to testify.

You expressed concern that this legislation would result in the creation of a new category of Medicaid eligibility. I would like to make several points in response. First let me say that I think part of the reason you and I have different perspectives on this issue is that we start from very different points. You seem to see Medicaid solely as a means-tested entitlement for the poor. While I agree, I also see Medicaid as a program where, at least based on Connecticut figures, over 40 percent of those who receive Medicaid long-term care services did not start out poor.

I hear of financial planners teaching seniors how to transfer their assets and access Medicaid benefits and I feel there ought to be a better way—a way which enables people to plan ahead to meet their long-term care needs without having to wipe out a lifetime of savings. Our society has changed markedly in the 25 years since the enactment of the Medicaid program to the point where many of those receiving Medicaid are not included in our traditional definition of "poor".

The current Medicaid long-term care program is a means-tested program in name only. The major asset most seniors possess is a house which is typically protected by Medicaid. Substantial income and asset protection for the "at-home" spouse is also offered. In fact, the Pepper Commission recommended that the nonhousing asset test be extended even further. Given the political pressures associated with the aging of the population, we are likely to see even more proposals to further increase the amount of assets exempted from Medicaid.

In that context, my proposal, which requires the individual to purchase private long-term care insurance if they desire additional asset protection, may be the ONLY proposal that has the potential of actually protecting Medicaid against further erosion of its means-tested origin.

The second point I would like to make is that the change that would occur as a result of enactment of these waivers is not that Medicaid would cease to be a means-tested program. Rather, Medicaid for the first time would provide a positive alternative for individuals who wish to protect assets, as opposed to forcing these individuals to passively wait for impoverishment in order to qualify.

In a recent analysis of the Connecticut proposal, Region I HCFA made the following comments: ". . . in the traditionally accepted view, the middle-class individual provides for his/her long-term care by gradually expending his/her resources out-of-pocket for the cost of long-term care as it is consumed. Eligibility for Medicaid does not exist until an individual's countable resources are reduced to the State's (or SSI's) countable resource limit. Thus, resources are reduced over time until the point at which Medicaid resource eligibility is reached.

"Conceptually, purchase and utilization of long-term care insurance is viewed by the designers of this demonstration as an equivalent assumption of responsibility for long-term care costs on the part of the individual. The individual in effect pays premiums to an insurance company out of his/her income/resources over a period of time prior to the need for long-term care, and through this risk-pooling arrangement, passes the risk of cost of long-term care to the insurance company. The Medicaid program is protected from additional expenditures to the extent that the insurance benefit pays out the same amount as the individual would have paid out-of-pocket for long-term care. If the insurance is in the same amount as the client's resources, this payout should theoretically defer the need for Medicaid, and concomitant Medicaid expenditure, to the same point in time that it would have been deferred had the individual used his/her liquid resources to directly pay the cost of long-term care."

You support that enactment of these waivers would result in "Medicaid being used to protect assets and, in effect, to finance the transfer of wealth from one generation to the next". I don't think so. It is sound public policy to encourage those with the financial means to do so, to anticipate their future needs and to take appropriate steps to plan for them. At the same time scarce public dollars should be used to protect the poor who may not have the financial means to protect themselves.

In this instance, I do not believe that Medicaid is being asked to finance the transfer of wealth, but rather, to encourage people to plan for and take care of themselves, with the promise that if their individual efforts fail, the government will continue to act as the insurer of last resort. These demonstrations will not result in additional Medicaid dollars being used to allow wealthy individual to qualify for Medicaid. Rather, the projects will delay or avoid Medicaid use by the middle class.

Further, Mr. Chairman, I am not proposing a permanent restructuring of the Medicaid program, but rather a test of the extent to which private insurance can help solve the long-term care financing problem. This is critical as all proposals currently before Congress that envision a role for private supplemental insurance.

This leads to your next concern which is whether this project is really a demonstration or an irrevocable decision on long-term care policy.

You are correct in noting that those individuals who enroll during the demonstration would receive a lasting promise of asset protection. Would you have it otherwise? I have not hesitated in saying that private insurance must be guaranteed renewable, shouldn't the public sector make a similar promise?

In addition, in a recent Op Ed in the Washington Post, Yale Professor George Silver used strong historical evidence to show that "when welfare and health legislation begin in the States, the effects of the law are tested and the laws amended, refined and polished." But "when Congress has taken the initiative without previous State laws as guides . . . the law is constantly being amended and mired in controversy."

Hence, I can make the case for State demonstrations before we embark on a comprehensive national program. These demonstrations will gather valuable service delivery system utilization and cost data which will be necessary in designing any social insurance approach to long-term health care. And I think that you will agree that if we learned anything from the Catastrophic Health Care experience, it is that we need better data before embarking on new programs of this magnitude, if only to assure better budget and revenue estimates.

Now, Mr. Chairman I understand that you are concerned that taken together these nine States contain 35 percent of the Nation's elderly and that perhaps given the lasting nature of the promise in these demonstrations and the percentage of the elderly population covered that enactment of this proposal would represent an irrevocable decision on long-term care policy.

I would like to suggest a solution; it would be possible to limit participation in each of the States to the greater of 50,000 people or 10 percent of its elderly population.

But let me make one point perfectly clear. Connecticut wants to be part of this demonstration. My constituents are clamoring for this Partnership. Virtually every analysis of these projects (including—I am told—the soon-to-be-released GAO Report) lists Connecticut as the project with the best potential for success.

Finally, Mr. Chairman, you raise the issue of insurance standards. [First I feel compelled to inform you that as a member of the Ways and Means Committee, the Committee considers this to be an issue where there is joint jurisdiction and as such you should know that I have also been discussing this aspect with Mr. Stark and Mr. Rostenkowski.]

I know this is an issue that this committee and your subcommittee have spent a great deal of time on and are very concerned about. Let me assure you that this is an issue that has been discussed at length in each State. Each of the nine States in question has long-term care insurance standards which exceed those recommended by the National Association of Insurance Commissioners.

Coverage is guaranteed renewable. Home care and inflation protection are offered. Policies cannot condition payment on prior hospitalization. Major education efforts are included. Each of these States, even outside of these demonstrations, has standards for assuring insurers' solvency. And again, Connecticut has been consistently sited as a model.

Now let me suggest the long-term care insurance is a complicated product. The appropriate regulatory standards that make long-term care attractive and protect the consumer, while at the same time giving insurers and regulators sufficient discretion to develop innovative products, are not always self-evident.

For instance, you maintain the necessity of a cash-value non-forfeiture benefit. Such a benefit would cause all policyholders to stop paying premiums just prior to death so they could recoup premiums paid to date. A prohibition against the use of medical underwriting would result in individuals already residing in a nursing home being eligible to purchase insurance, thereby undermining the establishment of a viable risk-pool and driving up premiums. We do need to keep in mind Mr. Chairman that these are supposed to be demonstrations on innovative long-term care financing involving the private sector, not comprehensive government programs. As you are well aware, the two often operate very differently.

One of the purposes of the pilot is to help States better understand just what the regulatory problems are so that appropriate regulatory solutions can be developed. And since you and I are in agreement that if this proposal is to be enacted, it be designed to be a true demonstration, let me suggest that comprehensive Federal standards that override State standards do not belong in a demonstration.

Perhaps a more workable solution would be a situation where the subcommittee reviews the standard in force in each State and includes language that requires that standards at least as strict as those reviewed by the subcommittee remain in effect for the duration of the waiver for these demonstration projects. In this way, the subcommittee would be assured that there are strict standards in place while State legislatures would be free to strengthen, but not weaken, the standards in response to market conditions.

Let me conclude by summarizing the general advantages of these demonstration projects. These demonstrations would provide individuals with a way to plan for their own long-term care needs.

The demonstrations have the potential to save Federal and State Medicaid dollars. The Connecticut micro-simulation showed both overall and long-term public savings. The demonstration would influence the type of coverage offered under private long-term care insurance. Precertification would only be available to policies which offer comprehensive care while discouraging inappropriate utilization.

Mr. Chairman I hope this information is helpful to you and the subcommittee in your deliberations. Your staff has expressed interest in having one individual to deal with who can speak for all the interested parties in attempting to reach a compromise on this issue. As the sponsor of this legislation, let me suggest that the most appropriate person would be Dr. Kevin Mahoney, the Connecticut Project Director. He has both the technical and political background as well as ties to the Foundation to work out any necessary compromises. I have every confidence in him.

Thank you Mr. Chairman. We are prepared to meet—at your earliest convenience—to discuss the specifics of my bill and a possible compromise. I would be happy to respond to any questions you may have.

Mr. WAXMAN. Last but not least, our colleague, Mr. Durbin.

STATEMENT OF HON. RICHARD J. DURBIN

Mr. DURBIN. Thank you, Mr. Chairman. I want to thank you for the fine work you do on these programs, but also so many health programs.

In the ebb and flow of political issues in our country, it seems in my congressional district and probably in most, that there is no issue of more concern and greater importance than the issue of health care.

Dr. Rowland and I came to Congress the same year. We have worked together on many efforts relative to infant mortality, and I know that Congressman Rowland served on the national commission investigating that insidious problem which our Nation faces.

What I have proposed here in this legislation, the Medicaid Outreach and Child Health Act of 1990, is an attempt to address one aspect of the problem.

I serve on the Budget Committee. I have a sneaky suspicion that secretly many people who are involved in the budget process hope that all of those who are eligible for Federal programs won't find them, because if in fact they do, it becomes more expensive.

I would suggest that we ought to take exactly the opposite approach when it comes to working with pregnant women and small children in America. We should go out and look for them. Because if we don't, as Dr. Rowland can testify, we will pay for decades to come the expenses of children who were not taken care of during a mother's pregnancy and thereafter.

That is why I have introduced this legislation cosponsored by Congresswoman Morella of Maryland and Mr. Miller of California. Let me tell you two or three things which I have included in there which I would like you to consider.

First, to provide a 75 percent Federal matching rate to States for the cost of outreach efforts to identify and enroll pregnant women and children who are eligible for Medicaid. This provision, because it increases the match to 75 percent, is going to encourage States to expand their outreach activities.

We all know that outreach increases the number of eligible people who actually receive Medicaid service. An enhanced match would give the States the incentive they need to go find these folks, and we want to see a real effort. It is one thing to put a poster in an office; it is another thing to go out and actually recruit and look for those who are eligible.

I suspect many times, and I think Congresswoman Collins has found in her district, too, that we have identified maybe the easiest people to bring into Medicaid, but the ones who need it the most are the ones we have to go out and search for to bring in and make certain that they receive the medical care that is necessary.

The second provision in the bill is one which I really have a strong feeling for and I hope if nothing else in my testimony, you will remember this when you consider Medicaid reform legislation. I am proposing to establish a $10 million Federal grant program to fund demonstration projects to increase the enrollment of eligible pregnant women and children in Medicaid.

This provision is going to fund outreach demonstration projects operated by private, nonprofit organizations and local public agencies which have strong community support, and they have demonstrated linkage to the communities serving low-income women and children.

There are two unique aspects to it. First, it places a special emphasis on reaching children, and I think that is somewhat unique in the law. Second, it has a special emphasis on community-based approaches to outreach.

I am sure that everyone on this panel is familiar with it. I hope that you have all read it, but the book by Lisbeth Schorr suggests that many of us who support these social programs should not be apologetic.

So many of those programs are successful. The key elements in successful community programs that provide social services are, first, to be community based, a grassroots operation; and second, that it have an outreach component.

I think putting this demonstration money into Medicaid, basing it on community-based organizations, is going to combine those two successful elements which Ms. Schorr in her book, and we have seen over and over to be successful.

There are two other elements to provide more secure coverage to promote child health which I think are important. First, a mandate of continuous eligibility for pregnant women for 60 days after giving birth and for eligible infants for 1 year after birth. Forty-four States have already adopted this standard. It should be universal. It should be national, and I am calling for a mandate to make certain that it is.

There is absolutely no excuse that a child would somehow lose eligibility 60 days after birth or the mother would not be taken care of during that period of time. I think that should be mandated.

Finally, the bill would establish a State option allowing States to continue Medicaid eligibility for children for a 1-year period.

Mr. Chairman, we have come a long way in our attention to the medical needs of low-income people and pregnant women and children. The job is surely not finished.

I hope in the course of our budget discussions, those of us who feel strongly about this issue will not lose sight of the fact that money invested in Medicaid and in health care is money well spent, and is actually money spent today to save money tomorrow.

Thank you.

[The prepared statement of Mr. Durbin follows:]

Prepared Statement of Hon. Richard J. Durbin, a Representative in Congress From the State of Illinois

Mr. Chairman, I would like to thank you for giving me the opportunity to testify today. You have taken the lead in the ongoing battle to expand access to health care, and many of the people who are today receiving the medical care they need have you to thank. In particular, many of the people who are now covered by Medicaid only have that assurance of medical assistance because of your persistent efforts to expand the program to cover the most vulnerable people in our nation.

I would like to focus today on the provisions of a bill I introduced last month which is designed to provide greater assurance that the Medicaid expansions you have worked on are as effective as possible in reaching the intended population.

The Medicaid Outreach and Child Health Act of 1990 (H.R. 5480), which I was pleased to be able to introduce with Mrs. Morella of Maryland and Mr. Miller of California, would strengthen our Nation's Medicaid program by improving our outreach efforts to pregnant women and children and by providing more secure Medicaid coverage for pregnant women and children who are already enrolled.

As you know, on April 1 of this year the provisions of OBRA–89 took effect which provide Medicaid coverage pregnant women and children up to age 6 with family incomes below 133 percent of the poverty level. This expansion is an important step in the effort to reduce infant mortality and improve child health, because it offers pregnant women and children the health care they need to foster a healthy birth and a good start in life.

The significant health care expansion passed last year will not achieve its full purpose if eligible people don't know they are eligible for Medicaid or encounter barriers that inhibit enrollment. Expanded Medicaid outreach efforts are essential to achieve the goals of the OBRA–89 expansions.

My legislation includes two provisions to address the need for outreach.

First, it would provide a 75% Federal matching rate to states for the cost of outreach efforts to identify and enroll pregnant women and children who are eligible for Medicaid. This provision would encourage states to expand their outreach activities. We all know that outreach increases the number of eligible people who actually receive Medicaid services, and that costs the states money. An enhanced match would give the states an additional incentive to make the effort to find those eligible people.

To ensure that outreach efforts are as effective as possible, my proposal would limit the enhanced match to states that go beyond public service announcements and activities in the local welfare office. It would limit the special match to states that station eligibility workers in public health clinics or other community locations outside of the county welfare office.

It isn't enough to set up a Medicaid program and say, "Here we are. Come battle the bureaucratic red tape and you can then see a doctor." The people we are trying to reach often don't know how to negotiate the system, or they have tried before and failed to obtain eligibility so they don't see why it is worth trying again. But we know that eligibility rules have changed. And we know that medical care during pregnancy is critical to the well-being of our future citizens. We simply must go out to people where they live, inform them about Medicaid, and assist them in applying for and then actually obtaining the services for which they are eligible.

The second provision in my bill responds to the fact that we still have a lot to learn about how to reach certain populations. I propose to establish a $10 million Federal grant program to fund demonstration projects to increase the enrollment of eligible pregnant women and children in Medicaid. This provision would fund outreach demonstration projects operated by private nonprofit organizations and local public agencies which have strong community support and demonstrated linkages to other community programs serving low-income women and children.

I have been told that only a small fraction of the children who were made eligible for Medicaid as a result of the recent expansions are actually receiving Medicaid services. And we know that there are still many pregnant women who do not receive medical care until late in their pregnancies, if at all. We need a demonstration program that will fund innovative approaches to increasing the participation of pregnant women and children in the Medicaid program.

This proposal is unique in two respects. First, it places a special emphasis on reaching children. This emphasis moves us beyond the approach we have taken in the past in Title V and other programs, where we have focused almost exclusively on pregnant women. We have a lot to learn about how to reach the parents of eligible children so that their children become Medicaid recipients. These demonstration programs would help us identify those methods that are most effective, so that they can be undertaken on a larger scale in future years.

The second way in which this proposal is unique is in its emphasis on community-based approaches to outreach. We have tended to focus in the past on Federal or state-based outreach, which usually means broad, media-oriented campaigns. But we all know that person-to-person contact is most effective in educating or motivating changes in a person's activities. And people are more receptive to the message and assistance provided by a respected organization that is active in the local neighborhood, rather than the message of an enormous bureaucracy. Similarly, it is person-to-person contact through local, community-based organizations that is most likely to reach people in a way that effectively informs them of their opportunities and helps them become enrolled in Medicaid and begin to receive medical services.

This demonstration grant program would fund projects that emphasize personal contacts with potentially eligible persons, and that do a little "hand-holding" if necessary to ensure that any potential barriers to enrollment are overcome. There is no substitute for the personal attention that a local, community-based organization can provide.

The Medicaid Outreach and Child Health Act also contains two other provisions that would improve the effectiveness of Medicaid and provide more secure coverage for pregnant women and children who are already enrolled. Similar provisions have been included in legislation that has been considered by the committee in the past.

The bill would mandate continuous Medicaid eligibility for pregnant women for 60 days after giving birth and for eligible infants for 1 year after birth. This would allow a pregnant woman who has established Medicaid eligibility to remain eligible until 60 days after giving birth, and would allow her newborn baby to remain eligible for 1 year after birth, even if a short-term rise in family income would otherwise bump her and the infant off the program and force them to reapply.

Currently, 44 states have adopted the existing Medicaid option that provides continuous eligibility for pregnant women for 60 days after giving birth and for infants for up to 1 year while the mother remains eligible. This provision would pick up the remaining 6 states.

In addition, it would address a problem that remains even in the 44 states that already have the continuous eligibility option. When a mother loses her eligibility for Medicaid 60 days after giving birth because the 133%-of-poverty provision no longer applies, her infant automatically loses eligibility as well and must reapply. Almost all of the infants are in fact still eligible, because the 133% of poverty level income standard that covered the mother remains in effect for children up to age 6. However, if a new application for the baby is not successfully completed, the baby loses Medicaid coverage. Even if the new application is made, reestablishing eligibility can often take several months, during which time the baby is not eligible for Medicaid. The continuous eligibility provision would ensure continued coverage of infants for a full year even when the mother loses eligibility after giving birth.

Finally, the bill would establish a state option allowing states to continue Medicaid eligibility for children for a 1-year period. This provision would give states the option of allowing children to maintain eligibility for a 1-year period when a change in income might otherwise terminate their eligibility for at least one month. Several states have expressed an interest in experimenting with this alternative approach to Medicaid eligibility.

This provision would reduce the amount of paperwork that is currently required by Medicaid's monthly income verification. Since the paperwork involved in establishing and maintaining enrollment in Medicaid is considered a significant deterrent to Medicaid enrollment, this approach could help in the effort to maintain Medicaid coverage for all eligible children. In addition, it would improve child health by eliminating some of the cycling on and off of Medicaid that causes children to miss crucial medical care that is essential to their healthy growth and development.

Mr. Chairman, we have come a long way in our attention to the medical needs of low-income children and pregnant women, but the job is not finished. Some of what needs to be done is contained in legislation you have championed that would further expand Medicaid coverage. But we also need to consolidate the gains we have already made. The four provisions I have outlined here today would move us closer toward the goal of ensuring that medical care is available to all of those people who have already been made eligible for Medicaid. I would ask that you and all of the members of the committee give careful attention to these provisions, and I hope that they can be included in legislation that the committee will be reporting later this year.

Again, thank you for giving me this opportunity to testify.

Mr. WAXMAN. I want to compliment you on your commitment to making the investment for women and children I think the best investment we can make in this country.

Let me see if our colleagues—Dr. Rowland.

Mr. ROWLAND. Thank you.

You are exactly right, that just because an individual is eligible for Medicaid doesn't mean that he is going to come in. There has got to be some way to reach these people.

Just this past week I was at home visiting a hospital there and asked a question: Are you still having women coming in who are eligible for Medicaid that have not received any prenatal care? And the answer is, yes, there is still a large number that come in and they have a below birth weight, and then the cost that is concomitant with that.

We know that for every dollar spent in giving good prenatal care and getting these children up to a good birth weight will save anywhere from $3 to $5 in later expenses.

So I commend you on the work that you have done, the interest that you have in this, and it is something that I have long been interested in and realized long before I came to Congress how important that is.

I thank you for what you do in this area.

Mr. DURBIN. Thank you, Congressman Rowland. I know we have an awful lot of things to read, but there are articles in yesterday's New York Times Magazine by Dr. T. Berry Brazelton, who is one of my heroes. It is almost incalculable for us to sit down and try to measure what it is going to cost us down the line if we don't make that investment today.

Mr. SCHEUER. I would just add that the way we treat our kids is one of the outrages and shames of American society. We have a $5½ trillion annual GNP and the fact that we are engaged in a consumer spending binge on VCR's and whatnot, the fact that we can't seem to get ourselves to tap that $5½ trillion resource to do the things we want to do, number one, enhancing the health and productivity and education and well-being of our kids to me is a blight on our country.

The fact that we are the richest country in the world and we are 20th in the world in infant mortality symbolizes that same, and I congratulate you, Congressman, for the fine work that you are doing.

Mrs. COLLINS. Let me associate myself with the remarks of my colleague, Dick Durbin, and say that I believe you have looked at this very, very carefully and your legislation certainly is a tremendous approach to resolving the kind of problem we have experienced. I myself have legislation very similar to yours, and think that we are both on the right track.

The one thing that I am most concerned about, as well as all the other problems that you have mentioned, is the fact that many times these low-birth-weight children whose mothers have had very little, if any, prenatal care find themselves at an academic disadvantage by the time they get ready to go to kindergarten.

The class of 2006, for example, is going to be at a tremendous disadvantage particularly as our whole global economy becomes more technologically advanced and so forth. Therefore, I think that for those academic reasons, in addition to the medical reasons that we all know about, we as a country have a responsibility to make sure that our future leaders are going to be right up there with all of the rest of the countries when it comes down to developing and maintaining a strong scientific, research and economic base for our world.

Thank you for your vision.

Mr. DURBIN. Thank you.

[The prepared statement of Mrs. Collins follows:]

PREPARED STATEMENT OF HON. CARDISS COLLINS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. Speaker, I commend you for calling today's hearing on this series of Medicaid initiatives. They are badly needed to plug the holes in the Medicaid system and provide health care relief where there now is little or none.

In February of this year, I joined you, Mr. Chairman, and other colleagues in introducing a series of Medicaid initiatives of which my bill, H.R. 3931, the Medicaid Infant Mortality Amendments of 1990, is a part. H.R. 3931 is aimed at one of the greatest health care plagues in the United States today. It is imperative that Medicaid coverage be expanded as called for in this bill.

Before the high school class of 2006 even enters kindergarten, academic achievement may be unattainable for many through no fault of their own but because they are the innocent victims of poor prenatal care, low birthweight and lack of routine health care. Very low birthweight babies and especially those born with the AIDS virus or alcohol and/or drug addictions are not only physically impaired but usually mentally impaired. It is one of the great ironies of our political system that the neglect of a sizeable population of children passes unnoticed.

"Quite simply, our social and political negligence is creating a generation of medically denied children, for whom we will all pay a very high price in the years to come," said William H. Considine, head of the Children's Hospital Medical Center in Akron, OH.

The United States is one of the wealthiest nations on earth and we are having trouble taking care of our own children. Undoubtedly, we need to reshuffle our priorities and redirect our attention to this shameful dilemma of infant mortality. In 1988, the United States ranked 19th worldwide on infant survival. The number of children in this country who die before their first birthday in painful, while the number who die before their fifth birthday is heartwrenching.

Of the 3.8 million infants born in the United States in 1987, 40,000 died by their first birthday. In Illinois alone, in 1987, 2,102 infants died before their first birthday. The infant mortality rate was 11.6 deaths per 1,000 live births, as compared to 10.1 for the Nation.

Black infants have an even greater chance of dying before their first birthday than their white counterparts. In 1986, Chicago ranked 14th out of 18 major cities for Black infant mortality with a rate of 22.9 deaths out of 1,000 live infants. This was compared to the 10.7 dead out of 1,000 live of white infants.

Poor and minority children are also more likely to suffer health-related problems. For instance, among 15- to 19-year olds, black teenagers have a birth rate nearly three times that of white teenagers, and the babies are twice as likely to be born with low birth weights.

Undoubtedly, the sources of this unfortunate dilemma are low birthweight, lack of prenatal care, and lack of routine health care (i.e. immunization). Low birthweight (birth at less than 5.5 pounds) is the single largest cause of infant death and a major cause of disability. In 1987, 13,370 or 7.4 percent of the 180,680 babies born in Illinois had a low birthweight. Excessively low birthweight costs the Nation millions of dollars each year. "If Johnny or Susie can't see properly or suffers the long-term effects of low birthweight, it's little wonder that the child can't read," said Robert H. Sweeney, president of the National Association of Children's Hospitals and Related Institutions.

There is no question that prenatal care can save lives and money. By detecting problems during pregnancy, prenatal care can help prevent low birthweight. Every $1 spent on prenatal care saves $3 off new-born costs. In 1987, only 78.5 percent of women in Illinois had the benefit of critical prenatal care.

Finally, immunization can prevent eight diseases that threaten our children. Childhood immunizations save $10 for every $1 we spend. Our failure to reach infants and toddlers with vaccines has led to disease outbreaks and preventable disability and death. Immunization rates for children under 2 are declining while cases of measles, mumps and whooping cough, are on the rise. Last year, there were 2,551 cases of measles in Illinois.

There must be something done to improve the health of our Nation's children. Today, only 60 percent of children younger than 4 years old have received the basic series of immunizations to avoid many common childhood diseases. While 60 percent of children as a whole were immunized against six or seven diseases, among non-white children, only 52 percent received immunization for measles and 51 percent were immunized for DPT.

The single most urgent directive is to improve children's access to health care. In 1986, uninsured children received 40 percent less physician care than their insured counterparts, regardless of their need for regular periodic assessments and immunizations. Today, one out of every five children has no health insurance, public or private. The key to ensuring care for our children lies in providing the necessary resources, public and/or private. Providing such care is the principal aim of H.R. 3931.

We must remember that our Nation's future competitiveness depends on the workforce we have in place. The time to act to ensure the quality of that workforce is NOW, not in the year 2000.

Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Scheuer.

Mr. SCHEUER. I can tell my colleague from Illinois that Congressman Dale Kildee and I are sponsoring a bill for full funding of the Head Start program, for its education benefits and also for its health benefits, full funding by 1994, which is the quickest that the school community thought they could gear up with the manpower, the skilled manpower to handle that program.

That would go a long way to fill the need that you have alluded to, Congressman Collins, making our kids learning ready by the time they hit school. Nothing is more important for the health of our country.

Mrs. COLLINS. It is only to be commended.

Mr. WAXMAN. Thank you very much.

We are pleased and honored to have as our next witness the mayor of New York City, and I will ask Mr. Scheuer to introduce him.

Mr. SCHEUER. Thank you, Mr. Chairman.

It is a great honor for me to introduce the great mayor of the city of New York, great by every standard of compassion, decency, inner strength, inner resources. The mayor, in a very few short months, has proven himself to be a great human being, a great leader, a man of great inner strength.

His own city has a Medicaid budget paying 25 percent of the cost of Medicaid in that city. Last year, as I recall, the city spent $1,128,000,000—$1.28 billion of its own funds—for Medicare. Now, that is more than any State in the country has spent, much less cities, except for California, Massachusetts and New York.

The city is facing major health challenges. It has the largest number of AIDS patients in the country. It has the largest number of homeless in the country. It has an overwhelming percentage of the drug addiction cases in the country, about 600,000 of them.

The city hospital system is at the point of physical collapse, because they are trying to do more in terms of serving people than they have the resources to do, and the city isn't getting enough help from the Federal Government, they aren't getting enough help from the State.

With all of these pressures, with the enormous fiscal pressure and with the competing pressures of the competing needs of the law enforcement system that we have all read about in recent days and weeks and months, with all of that, the mayor continues to lead in terms of investment in our human services, in our health services, in our child care services. And he hasn't been distracted by the enormous fiscal pressures of the city, by the legitimate and rightful claims of the law enforcement community.

He has made some very touch choices. He is no stranger to tough choices and by investing in maternal and child health and investing in all of these, particularly the health care in Harlem Hospital, of infants born with AIDS, infants born of drug-addicted mothers, AIDS-addicted mothers. He is showing enormous leadership, enormous compassion in addressing himself to those programs, with courage, with dignity, and devoting resources to them, too, which does you great credit, Mr. Mayor.

We are delighted to have you. Your written statement, of course, will be included in the record, and I take it the chairman would say please proceed with your testimony.

Mr. WAXMAN. We are delighted to have you here.

STATEMENT OF DAVID N. DINKINS, MAYOR, CITY OF NEW YORK

Mr. DINKINS. Thank you very much, Mr. Chairman. Dean Scheuer, thank you for your overly generous remarks. I am very pleased to have this opportunity. I am happy to be here with Dr. Rowland and Mrs. Collins, Mr. Wyden, distinguished members of our Congress, and I thank you all for the opportunity to appear before you this morning.

I am here today to lend my support to four measures under consideration by the Health and Environment Subcommittee. These four measures, if adopted, would not only provide far reaching benefits to those who are the subject of these proposals, but would also render a practical and noble service to the people of our country, both urban and rural dwellers.

The architects of these bills, in particular Congressman Waxman, Congressman Scheuer, Congressman Towns, Congressman Slattery and Congresswoman Collins, are to be congratulated. They constructed these pieces of legislation with precision. Each of these measures addresses specific and dramatic need.

These proposals must be priorities in the Federal budget for fiscal year 1991 because they address life and death issues that determine both the survival and the quality of life of our most vulnerable communities.

The city of New York endorses these measures because they demonstrate a sound commitment to the medical and fiscal needs of all Americans. They are designed with insight and are not motivated by a grand-scale or grandstanding desire to expand Medicaid.

These sound measures have both immediate and long-term benefits. By targeting critical health care issues relative to individuals who test HIV-positive, pregnant women, infants, children, adolescents and drug and alcohol-affected families we directly serve populations in desperate need of expanded medical services. The benefactions bestowed upon us in the present, however, will continue well into the future since they will keep the citizens of this country ablebodied.

Fiscally, the measures before you spend reasonably in the present, so that we will not be obliged to spend extravagantly in the future. There is an old adage, "An ounce of prevention is worth a pound of cure." If ever this idea applied, it applies here.

The Medicaid AIDS and HIV Amendments of 1990, H.R. 4080, introduced by Congressmen Scheuer and Waxman, are a case in point. This bill of compassion recognizes human suffering and seeks to ease it; the legislation also recognizes fiscal wisdom, and embraces it.

The legislation, by allowing medical treatment for HIV-positive individuals before they develop AIDS, provides help at a time when treatment is likely to bring the best results. By expanding the Medicaid reimbursement to include early preventive treatment, we save lives and engender hope.

I may add that we would have liked this legislation to include coverage of counseling and support services. The psychiatric trauma of a positive-HIV diagnosis can be devastating, and we should move compassionately and quickly to ease the pain. We are pleased that the bill acknowledges a need for enhanced reimbursement rates for hospitals with a disproportionate share of AIDS patients.

We are also very pleased with the measure's call for continuation of COBRA coverage. Such coverage allows individuals to remain independent longer, to maintain their own fiscal financial stability as they struggle to avoid progression of the disease. It is both fiscally sound and fundamentally humane.

Finally, we strongly endorse this bill's approach to the treatment of children hospitalized with AIDS and other critical illnesses. This measure would allow children to leave the hospital to be treated in home or home-like settings.

This is precisely the kind of Federal support we need, because it reinforces our own administration's priority to strengthen community and neighborhood-based services. Strengthening local communities is exactly what the Medicaid Family Care Act of 1990, H.R. 5536, introduced by Congressman Ed Towns, will achieve.

New York City is immensely pleased that this legislation takes a comprehensive view of drug treatment, with special focus upon the family. By allowing pregnant women and women with young children to receive Medicaid coverage for residential treatment and special support service, we assure that a mother will be offered the opportunity and skills to make a break from drug and alcohol dependency, and that the proper care will be given to her children.

The current categorical and bloc grant programs are not able to meet these needs. It is the genius of this bill that it synchronizes a woman's desire to be healthy with the overmastering desire of caring for her children.

Of the 600,000 drug users in New York City, at least half are women. The number of births to drug-using women increased by 437 percent from 1981 to 1988.

I know that the magnitude of this tragedy is not unique to New York City. This modest Medicaid proposal is the correct approach to a complex problem which is tearing apart our families and communities. Expanded treatment provided in H.R. 5536 would prevent the breakup of addiction-affected families and resulting social costs.

Similarly, I urge committee members to court H.R. 3931, the Medicaid Infant Mortality Amendments of 1990. I urge adoption of the bill because I know how effective its proposed care for pregnant women and infants can be.

Many of these provisions are already in place in New York City. By spending money at the start of a person's life, by providing early diagnosis of impending problems, early treatment and care, we save money in the long run.

The report of the White House Task Force on Infant Mortality in the United States says:

> By applying the knowledge it already has, the country could prevent an additional 10,000 infant deaths and an estimated 100,000 disabling conditions in the newborn.

A 1985 study by the Institute of Medicine found that for every dollar spent on prenatal care for certain higher risk women, as the Doctor just observed, $3.38 in total cost of care for low-birth-weight infants is saved.

We strongly endorse the outreach component of this bill. We all know of good programs that languished not for lack of funding, but simply because people didn't even know they existed.

As mayor of a city that already provides many of these benefit, I can personally attest to the vital importance of this bill, and I urge its adoption.

We know that prenatal care saves lives. It is a need for expanded access to this critical service that this bill so importantly emphasizes. The provisions of H.R. 3932, the Medicaid Child Health Amendments of 1990, in addition to covering elementary school age children, help to bring the ambit of health care that age group so often neglects, adolescents.

We would prefer to see children have access to this program up to the age of 21, but certainly the inclusion of those up to 18 is an important step, as is the mandated coverage of children whose families fall below the poverty level.

We also support the bill's call for optional coverage of children above the poverty level. This leaves the States free to seek mechanisms other than the Medicaid program for financing the care of this population. New York is now exploring alternatives, with a strong disposition towards selecting one that obliges employers to share more responsibility for health care insurance.

Medicaid should not be the primary insurer of employed individuals of moderate means. In conclusion, I urge support for these measures. They meet the fundamental criteria of good government programs. They are fiscally wise and humanly inspired.

I thank you again. I very much appreciate this opportunity to be heard. Thank you, sir.

[The prepared statement of Mr. Dinkins follows:]

PREPARED STATEMENT OF MAYOR DAVID N. DINKINS, CITY OF NEW YORK

Good morning Chairman Waxman and distinguished members of this subcommittee. I am here today to lend my support to four measures under consideration by the Health and the Environment Subcommittee.

These four measures—if adopted—would provide not only far-reaching beneifts to targeted constituencies, but would render a practical and noble service to the people of our country, both urban and rural dwellers.

The architects of these bills—in particular Congressman Waxman, Congressman Scheuer, Congressman Towns, Congressman Slattery and Congresswoman Collins—are to be congratulated. They constructed these pieces of legislation with precision. Each of these measures addresses a specific and dramatic need.

These proposals must be priorities in the Federal budget for fiscal year 1991 because they address life and death issues that determine both the survival and the quality of life of our most vulnerable communities.

The City of New York endorses these measures because they demonstrate a sound commitment to the medical and fiscal needs of all Americans. They are designed with insight and are not motivated by a grand-scale or grand-standing desire to expand Medicaid.

These sound measures have both immediate and long-term benefits. By targeting critical health-care issues relative to individuals who test HIV-positive, pregnant women, infants, children, adolescents and drug- and alcohol-affected families we directly serve populations in desperate need of expanded medical services. The benefactions bestowed upon us in the present, however, will continue well into the future since they will keep the citizens of this country ablebodied.

Fiscally, the measures before you spend reasonably in the present, so that we will not be obliged to spend extravagantly in the future. There is an old adage—a penny's worth of prevention is worth a pound of cure. If ever this idea applied, it applies here.

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The legislation, by allowing medical treatment for HIV-positive individuals before they develop AIDS, provides help at a time when treatment is likely to bring the best results. By expanding the Medicaid reimbursement to include early prophylactic treatment, we save lives and engender hope.

I may add that we would have liked this legislation to include coverage of counseling and support services. The psychiatric trauma of a positive-HIV diagnosis can be devastating, and we should move compassionately and quickly to ease the pain. We are pleased that the bill acknowledges a need for enhanced reimbursement rates for hospitals with a disproportionate share of AIDS patients.

We are also very pleased with the measure's call for continuation of COBRA coverage. Such coverage allows individuals to remain independent longer, and enables a continuity of care. Finally, we strongly endorse this bill's allowance for optional State coverage of home- or community-based services for children with AIDS. It is one of my administration's highest health priorities to strengthen community- and neighborhood-based services.

Strengthening local communities is exactly what the Medicaid Family Care Act of 1990, H.R. 5536, introduced by Congressman Towns, will achieve. New York City is immensely pleased that this legislation takes a comprehensive view of drug treatment, with special focus upon the family. By allowing pregnant women and women with young children to receive Medicaid coverage for residential treatment and essential support services, we assure that a mother will be offered the opportunity and skills to make a break from drug and alcohol dependency, and that the proper care will be given to her children.

The current categorical and block grant programs are not able to meet these needs. It is the genius of this bill that it synchronizes a woman's desire to be healthy with the overmastering desire of caring for her children. Of the 600,000 drug users in New York City, at least half are women. The number of births to drug-using women increased by 437 percent from 1981 to 1988. I know that the magnitude of this tragedy is not unique to New York City. This modest Medicaid proposal is the correct approach to a complex problem which is tearing apart our families and communities. The expanded treatment provided for in H.R. 5536 would prevent the breakup of addiction-affected families and the resulting social cost. Similarly, I urge committee members to support H.R. 3931, the Medicaid Infant Mortality Amendments of 1990. I urge adoption of the bill because I know how effective its proposed care for pregnant women and infants can be. Many of these provisions are in place in New York City.

By spending money at the start of a person's life—by providing early diagnoses of impending problems, early treatment and care—we save money in the long run. The Report of the White House Task Force on Infant Mortality in the United States, states that, "By applying the knowledge it already has, the country could prevent an additional 10,000 infant deaths and an estimated 100,000 disabling conditions in the newborn."

A 1985 study by the Institute of Medicine found that, for every dollar spent on prenatal care for certain high-risk women, we saved $3.38 in total costs of care for low-birthweight infants. We strongly endorse the outreach component of this bill. We all know of good programs that launched not for lack of funding, but simply because people didn't even know they existed.

As mayor of a city that already provides many of these benefits, I can personally attest to the vital importance of this bill, and I urge its adoption. We know that prenatal care saves lives. It is the need for expanded access to this critical service that this bill so importantly emphasizes.

The provisions of H.R. 3932, the Medicare Child Health Amendments of 1990, in addition to covering elementary schoolaged children, help to bring the ambit of health care that age group so often neglected—adolescents. We would prefer to see children have access to this program up to the age of 21, but certainly the inclusion of those up to 18 is an important step, as is the mandated coverage of children whose families fall under 100 percent of the poverty level.

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We also support the bill's call for optional coverage of children above the poverty level. This leaves the States free to seek mechanisms other than the Medicaid program for financing this population. New York is now exploring alternatives, with a strong disposition to selecting one that obliges employers to share more responsibility for health care insurance. Medicaid should not be the primary insurer of employed individuals of moderate means.

In conclusion, I urge support for these measures. They meet the fundamental criteria of good government programs: they are fiscally wise and humanely inspied. Thank you.

Mr. Waxman. Mayor Dinkins, I want to thank you for a statement that covered the whole range of Medicaid issues that are before us. All these various initiatives are quite modest scope when we recognize the health care needs in this country of those millions who have no coverage whatsoever.

They are often poor people, but not poor enough for Medicaid. Even when they are eligible for Medicaid, they are not eligible for some of these services that are so direly needed.

I thank you, and I particularly want to single out the fact that you were willing to come in and support the Collins Infant Mortality Amendment and the Slattery Amendment extending Medicaid to children. Unfortunately there are a lot of leaders at the State level who have opposed, who have Medicaid budgets far less than yours who have come in and opposed this particular—these particular proposals.

I want to commend you for your statement and for your support for these two bills and all the other bills that you have mentioned.

Mr. Dinkins. Thank you, sir.

Mr. Waxman. Mr. Scheuer, I am going to call on you first.

Mr. Scheuer. Thank you, Mr. Chairman.

I want to commend you for that fine statement, Mr. Mayor, and ask you what do you—how do you perceive of the future of our city if you can't get at least this minimal level of assistance on these awesome health problems that afflict us, particularly with our youth?

Mr. Dinkins. Well, I think that part of what is necessary is somehow or other we have got to convey the word, we collectively have got to convey the word, we collectively have got to convey the word to the populace in general through the media, of course, that is our best vehicle for getting the word out, that these things in addition to being humane and moral, really the correct and proper thing to do, but they are also cost-effective.

I argue often that while it is not always possible to make an appeal to conscience along moral lines, say this is the fair and just thing to do, it is not difficult to argue the physical side of this, and so those—not to suggest that people are motivated only by fiscal considerations, but clearly when you combine the two and they come together, we can demonstrate what it costs to are for a child born low birth weight that could stay in the hospital a very long time, and upwards—well approaching big numbers per day, depending on the city.

It could be anywhere from $300 or $400 to $1,000 a day, big, big numbers, and yet the cost of adequate prenatal care, which will decrease the chances of that child being born low birth weight are very, very low.

It is the smart thing to do, and we have failed to do it, we as a society. I think the part of the answer is to continue to hammer away at what we know to be correct, and sooner or later the people will understand. It is not a popular theme. It is one I thought of for a long time, long before I thought of running for the mayor of New York. I support it as the president of the bureau of Manhattan.

I am proud of the facility they have at Harlem Hospital that I helped fund as Manhattan borough president. It makes a difference. If you are a father and a grandfather, as I am, if you love children as I do, I cannot see how people cannot be moved by the plight of these youngsters.

Mr. SCHEUER. With the marvelous child health care center at Harlem Hospital and a former aide of mine now runs it, why is it that young women in Harlem don't avail themselves of those services—prenatal, postnatal, aides, drug addiction?

Mr. DINKINS. Part of what we do, as I observed in my comments and as others have observed, part of what we must do, we in Government, we must do a better job of getting the word out and letting people know that such provisions as have been made in the law and such things as are available, we have got to let people know that they are so that they will make use of them.

We can improve clearly a whole lot on what we do, but we also need greater resources.

Mr. SCHEUER. Thank you, Mr. Mayor.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. Just one question. I, too, want to commend you on an excellent presentation, Mr. Mayor, very helpful. My question to you is really one in terms of a mayor's orientation.

When I came to Congress, when we would have someone like yourself, a leader of a major city, the priorities always seemed to be in the area of infrastructure as it related to capital plant.

It might be a subway system, maybe dredging of a river or something of that nature. My sense is over the last few years that the priorities have really shifted to the human services side. Where, in your opinion, does Medicaid fit in terms of the priority for the domestic spending dollar at this point?

Mr. DINKINS. Very high. Very high. The need, obviously—I say obviously, is to find balance. I mean, I understand the need to deal with infrastructure. Indeed, we use great care in our capital program to recognizing that we could only do so much because as you increase your capital program you increase the expense side because you have got to fund it, and you have got to pay that set service, and as was the case in the fiscal year in which we now are, we had a $1.8 billion budget gap, so obviously you have got to balance, but it is essential, I say, that we recognize that in education and human services if we fail to provide in these areas, we fail everywhere, and I sometimes get the impression that the general public, they concentrate on what is bothering them at the moment.

For those of us in positions of responsibility, we somehow or other must have the courage and the vision to look down the road a bit because if we fail to provide for these children coming along now, for instance in New York we put one-fourth of our total budget in education, one fourth, and it still isn't enough.

We complain that we don't get enough from our State government in terms of the State aid formula for education, but we still must try to do what we can do. Today is the first day of school, and in the normal course that is where I would be, you know, attending, symbolically two or three schools, but fortunately I have got a bride of 37 years and my wife is doing that for me.

She is part of a 100 percent effort, get 100 percent of children to attend the first day of school, but I thought it was so important that I be here to express my views in this area that I decided to forego that opportunity, but you are right, we do—we care about infrastructure, obviously, and fiscal stability is essential or you can't do any of these things, no matter how you would prioritize them, and so we try to do that in New York.

We are proud of the fact that in difficult times we have nonetheless done those things. There is a minister, Dr. Gardner-Taylor, senior clergyman in Brooklyn, who says to me, "Dave, you have got to bite bullets and butter biscuits, and that is what I am trying to do."

Mr. Wyden. Well, I appreciate your answer.

I know that it is always more glamorous in politics to pour concrete and to cut ribbons.

Mr. Dinkins. It sure is.

Mr. Wyden. And launch capital projects. My own view is we ought to be focusing on the human needs gap at this point. I commend you for thinking of that. Thank you, Mr. Chairman.

Mr. Waxman. Mrs. Collins.

Mr. Collins. I also commend you for a thoughtful statement, Mr. Mayor. I very much appreciate the fact that you mentioned low-birth-weight babies. Their well-being is something that I am primarily concerned with, although I am concerned with the health of all born and unborn children.

It is such a vital thing. The reason for my concern stems from the fact that some few months ago I went to the University of Illinois Hospital in Chicago, and I went to the low-birth-weight section of this nursery and saw babies barely the size of my hand. That had such a tremendous impact on me that I just couldn't believe it, and I raised questions about how can these babies live. How can they survive? What will they be like, how will they develop medically and healthily and so on.

And when you made comments about my legislation it certainly was rewarding to me because there is such a tremendous need. I want to say, Mr. Chairman, that if the members of our subcommittee have not seen low-birth-weight babies, they ought to go to a hospital nursery and see for themselves exactly what we are talking about and the tragedy that we are talking about regarding these new lives, many of whom weigh hardly a pound, hardly a pound, maybe a pound and a half. Mr. Mayor, you are to be commended for your vision and for your foresight in recognizing this problem and for being here today to express your vital concern about the legislation that we are going to try to write.

I yield back the balance of my time.

Mr. Waxman. Thank you very much. Dr. Rowland.

Mr. Rowland. Thank you, Mr. Chairman.

I really appreciate you coming, Mr. Mayor. I know it took a real effort to get here and I really appreciate your testimony and the comments that you made. I have had a chance to visit New York as a member of the National Aids Commission and as a member of the National Commission to Prevent Infant Mortality, and I know exactly what you are experiencing there.

The basic problem is the same in rural areas, too. I represent a large rural area. The problems are basically the same. You made a statement that I think is so true. To paraphrase that, people don't respond to something unless it affects them immediately and personally, and so I think it is so important, people in positions of responsibility to continue to keep the pressure on.

Some people are not affected by the AIDS issue or are not affected by low-birth-weight infants, they think. They really are affected by it, but they don't think they are affected by it, so I really appreciate your taking the tie to come and the testimony that you have given.

Mr. Dinkins. Thank you, sir.

Mr. Waxman. Thank you, Dr. Rowland.

Mr. Mayor, we very much appreciate your willingness to be here and to, by your testimony and by your presence, underscore the need for these very important human services.

Mr. Dinkins. Thank you, sir.

It is really the other way around. I congratulate all of you. You are terrific.

Mr. Waxman. Our next panel consists of advocates for the beneficiary groups whose needs are addressed by the Medicaid initiatives in the House budget resolution. Kay Johnson is the Director of the Health Division at Children's Defense Fund. She will speak to the Medicaid Infant Mortality Amendment, H.R. 3932, and the Medicaid Child Health Amendments, H.R. 3932.

Richard Gehring is the chairman of the Board of Directors of the Alzheimer's Association. He will speak to the Medicaid Frail Elderly Community Care Amendments, H.R. 3933. Bill Jones represents the Consortium for Citizens with Disabilities. He will testify on the Medicaid Community Habilitation Services Amendment, H.R. 3934.

Jean McGuire is Executive Director of the AIDS Action Council. She will speak to the Medicaid AIDS and HIV Amendments, H.R. 4080. I want to thank each of you for being here this morning.

Your prepared statements are going to be in the record. What we would like to ask you to do is to limit your oral presentation to no more than 5 minutes. Before I start the testimony, I would like to insert in the record at this point the statement of Marty Pratt, President of Voice of the Retarded.

[The information follows:]

Voice of the Retarded,
Rolling Meadows, IL, September 7, 1990.

Hon. Henry A. Waxman,
Chairman, Subcommittee, Health and the Environment,
Committee on Energy and Commerce, Washington, DC.

Dear Representative Waxman: The Voice of the Retarded, the national organization representing guardians, relatives and friends of mentally retarded persons residing in more than 90 large residential facilities, throughout the United States, supports the enactment of H.R. 3934 as published on February 1, 1990. H.R. 3934 is similar to S. 1088; its companion bill in the Senate.

Voice of the Retarded supports H.R. 3934 as the bill does the following:

(1) Creates and optional, statewide medical assistance program for all developmentally disabled persons.

(2) Requires appropriate standards and controls for all types of residential facilities, regardless of location of size.

(3) Achieves the objectives of independence, productivity and integration for all developmentally disabled persons.

(4) Recognizes the urgent need to continue what will be termed "Habilitation Facility Services", and

(5) Develops a comprehensive, continuum of services for all developmentally disabled persons, rather than all "severely disabled persons", or other specifically defined disability groups.

(The absence of Medicaid services for other groups is not a matter of "Medical Reform", which relates to a "bias" in the current Medicaid program; but rather to a worthy proposal for creating additional, urgently needed services, a subject which is best addressed on its own merits.)

(6) Preserves the principle of freedom of choice of service providers which is currently a part of the Medicaid program.

(7) Omits all "freeze" or "size" limitations with regard to residential facilities for the developmentally disabled.

(8) Replaces currently overly excessive "downsizing" programs with objective planning, thereby truly serving the best interest of all developmentally disabled persons.

(9) Utilizes current Federal agencies and personnel, rather than creating another "Bureau" to service developmentally disabled persons.

(10) Provides the Secretary of Health and Human Services with sufficient authority to oversee the program, rather than attempting to limit participation by the Secretary.

(11) Establishes a reasonable program, at reasonable cost.

(12) In general, achieves the objective of "Medicare Reform" as this concept relate to developmentally disabled persons and the alleged "bias" in favor of so-called "large facilities".

Voice of the Retarded expresses its sincere appreciation to you and the members of the Subcommittee on Health for developing this outstanding piece of legislation in a very complicated, yet urgently needed area of services for developmentally disabled persons.

Sincerely,

Marty Pratt,
President, Voice of the Retarded, Inc.

Mr. **Waxman**. Miss Johnson, why don't we begin with you.

STATEMENTS OF KAY JOHNSON, DIRECTOR, HEALTH DIVISION, CHILDREN'S DEFENSE FUND; RICHARD GEHRING, CHAIR, BOARD OF DIRECTORS, ALZHEIMER'S ASSOCIATION; WILLIAM E. JONES, EXECUTIVE DIRECTOR, AMERICAN ASSOCIATION OF UNIVERSITY AFFILIATED PROGRAMS FOR PERSONS WITH DEVELOPMENTAL DISABILITIES, ON BEHALF OF CONSORTIUM FOR CITIZENS WITH DISABILITIES; AND JEAN F. McGUIRE, EXECUTIVE DIRECTOR, AIDS ACTION COUNCIL

Ms. **Johnson**. Mr. Chairman and members of the committee, on behalf of the Children's Defense Fund, I want to thank you for the opportunity to testify today regarding Medicaid improvements and their impact on the health of children.

For nearly 20 years CDF's health division has worked to improve poor children's access to health care, including primary and preventative services, as well as medical care for special health needs.

We commend you, Mr. Chairman, for holding this hearing today to focus attention on Medicaid, the Nation's largest, publicly financed health program for children. For millions of low income families, Medicaid has become the key to adequate access to needed health care.

However, we know that erosions in family income, health insurance, and health status have led to widening cracks in our health care system which the current Medicaid program has been unable to fill.

Mr. Chairman, we know that good health begins prior to the birth with comprehensive maternity care. However, every year thousands of infants are born too small or too soon.

Thousands of others will leave the hospital after birth only to go home to lives filled with health hazards, and these findings are highlighted in the White House Task Force report on infant mortality.

One quarter of nearly the 4 million babies born each year are born to poor families. Another 20 percent are born to families with incomes between 100 and 185 percent of the poverty level. This means that nearly half of all U.S. babies annually are born to low income families, those most likely to have no health insurance.

We also know that nearly 40,000 infants die before reaching their first birthday and another 400,000 will live on to develop a chronic or disabling condition, and much of this death and disability is preventable.

The White House Task Force report also found that in a given year, by applying the knowledge it already has, this Nation can prevent an additional 10,000 infant deaths and an estimated 100,000 disabling conditions in the newborn.

After birth we know that health risks continue. As a result of their compromised health status, the poorest 5- to 17-year-olds lose one and a half times more days of school because of acute or chronic health conditions, and we know that more children are twice as likely as their affluent counterparts to experience activity limitations and disabilities.

Adequate access to health care is critical to protecting the health of these women and children, yet in 1988 one in four babies nationwide was born to a mother who did not benefit from early care and that year marked the ninth year in a row in which the trend in receipt of late or no care actually worsened or showed no improvement.

In 1988 there were 73,000 infants born without benefit of any prenatal care whatsoever. We know for children that comprehensive primary preventative care can make a difference, and yet poor children are three times more likely than affluent children never to have had a physician visit and four times more likely never to have had a visit to a dentist.

In recent years Congress has taken steps to improve access to health care for pregnant women, infants and children, and the

Medicaid program is the primary health care financing program for these groups.

Because of the importance of adequate health care coverage and the size and scope of the program, changes in the Medicaid program are the most significant of the material and child health policy reforms made in the 1980's. However, despite these recent improvements, we have enormous gaps, particularly for children.

For example, Federal eligibility roles currently do not allow coverage of poor children older than seven with family incomes below State AFDC eligibility levels, and on average that means that these families make less than $5,000 per year for a family of three.

That leaves an estimated 2.5 to 3 million poor school age children with no health insurance, public or private. We believe that steps should be taken this year to improve this and other major challenges to low income families, that the Medicaid program should be expanded to cover all poor children through legislation such as H.R. 3932, where we have a phasein of bringing poor children in over the next 10 years.

We feel, Mr. Chairman, this is the minimum commitment that this Nation can make. We are not talking about bringing all poor children into the program next year.

We are talking about a decade in which we will make a commitment in this Nation to bring poor children into the program. We also believe that through legislation such as H.R. 3931 Medicaid coverage should be provided to all pregnant women and infants with family incomes below 185 percent of the Federal poverty level, that Federal funding should be provided to permit States to improve their Medicaid programs in a number of additional ways.

For example, in H.R. 5480, introduced by Representative Durbin, which we heard described earlier, we see the ability of States to provide continuous coverage to pregnant women and infants to allow annual enrollment periods children similar to those benefits that middle-class children are given through workplace coverage where children are enrolled once a year and they stay in as long as their parents are in that program for the entire year, and also to create community-based outreach programs.

We have done a lot at the Federal level. There has been a lot of effort to make States reach out. We also believe community outreach is essential. Finally, Medicaid drug treatment for families should be a priority. In H.R. 5536, as introduced by Representative Towns, we could give States the option to cover comprehensive residential alcohol and drug treatment service to pregnant women and children.

Current law precludes coverage for those nonhospital residential drug treatment programs we strongly support all of these measures and have included a number of other technical matters in the written statement.

Thank you.

[Testimony resumes on p. 96.]

[The prepared statement and attachments of Ms. Johnson follow:]

Testimony of the Children's Defense Fund

Prepared by
Kay Johnson
Director, Health Division

and

Sara Rosenbaum
Director, Programs and Policies Department

Mr. Chairman and Members of the Committee:

On behalf of the Children's Defense Fund (CDF), I want to thank you for this opportunity to testify today regarding Medicaid improvements and their impact on the health of children. The Children's Defense Fund exists to provide a strong and effective voice for the children of America who cannot vote, lobby, or speak for themselves. We pay particular attention to the needs of low income and minority children. For nearly 20 years, CDF's health division has worked to improve poor children's access to health care, including primary and preventive services, as well as medical care for special health care needs.

We commend you, Mr. Chairman, for holding this hearing today to focus attention on Medicaid -- the nation's largest publicly financed health program for children. For millions of low income families, Medicaid has been the key to adequate access to needed health care. However, erosions in family income, health insurance, and health status have led to widening cracks in our health care system which the current Medicaid program has been unable to fill.

In order to appreciate the barriers to health care services which exist for children, one must consider the following questions:

- What is the health status of children and pregnant women?
- What is the relationship between health insurance coverage, health care utilization, and health status?
- What reforms are needed to improve the adequacy of Medicaid coverage for low income families?

In the interest of time, I will briefly summarize my testimony today. However, I would like to submit a complete written statement for the record.

1. WHAT IS THE HEALTH STATUS OF CHILDREN AND PREGNANT WOMEN?

Good health begins prior to birth with comprehensive maternity care. However, each year hundreds of thousands of infants are born too small or too soon. Thousands of others will leave the hospital after birth only to go home to lives filled with health hazards. These facts are highlighted in the findings of the White House Task Force Report on Infant Mortality.[1]

- One-quarter of the nearly four million babies born each year are born to poor families. Another 20 percent are born to families with incomes between 100 and 185 percent of poverty. This means that nearly half of all U.S. births annually are to low income families--those most likely to be without health insurance and to live in medically underserved areas.
- Nearly 40,000 infants die before reaching their first birthday, while another 400,000 will develop a chronic or disabling condition.
- The single most significant factor in predicting infant health and survival is birthweight. Infants born at low birthweight (weighing less than 5.5 pounds) are about 20 times more likely to die in the first year of life as those born at average weight.

Much of this death and disability is preventable. The White House Task Force Report on Infant Mortality also found that in a given year: "By applying the knowledge it already has this country can prevent an additional 10,000 infant deaths and an estimated 100,000 disabling conditions in the newborn."

Recently released national birth statistics for 1988,[2] underscore the importance of these findings. The data reveal that the nation's progress in improving infant health continues to be inadequate.

- **No progress** has been made toward reducing low birthweight births, the leading cause of infant death. The proportion of all infants born at low birthweight was 6.9 percent in 1988, the same as the proportion in 1979. In all, more than 270,000 infants were born too small that year.
- In 1988, the proportion of black infants born at low birthweight continued an **upward trend** which began in 1986. For the first time since 1983, the ratio of black to white infants with low birthweight widened. The widest black/white gap since 1969 was recorded in low birthweight rates.

After birth, tens of thousands of even non-disabled children remain at risk for severe health problems. Poverty is a significant contributor to their health risks. In fact, the disparities between the health status of poor and affluent children widen with age. National Health Interview survey statistics for 1988 provide a disturbing picture of children's health status.[3]

- Children younger than 5 living in the poorest families (with annual family incomes less than $10,000) are about one-third less likely than children in affluent families (with incomes greater than $35,000) to be in excellent health (42 percent and 64 percent, respectively).
- Among children ages 5 to 17, this health status gap is even wider--with only 36 percent of poor school age children reporting excellent health as compared to 63 percent of affluent children.
- As a result of their compromised health status, the poorest 5 to 17 year olds lose 1.5 times more days of school because of acute or chronic health conditions.

In addition, a small proportion of all children suffer from one or more chronic impairments resulting in a significant loss of daily functioning. Included in this group are children with multiple physical and mental disabilities and chronic conditions, degenerative illnesses, and major orthopedic impairments, as well as technology-dependent children.

- In 1988, poor children were twice as likely than their affluent counterparts to experience activity limitations due to chronic conditions (8.8 versus 4.0 percent).

2. WHAT IS THE RELATIONSHIP BETWEEN INSURANCE STATUS, HEALTH CARE UTILIZATION, AND HEALTH STATUS?

Use of Health Services by Pregnant Women and Children

Adequate access to health care is critical to protecting maternal and child health and to saving money by preventing unnecessary illness, disability, and death.

Maternity care, beginning with prenatal care in the critical first three months of pregnancy and continuing until and beyond the birth of a child, can dramatically improve maternal and infant health. An infant born to a women receiving no prenatal care is more than 3 times more likely to die in the first year of life.[4] Prenatal care can save $3 for every $1 invested.[5] The White House Task Force Report indicates that each infant death cost this nation $380,000. Yet each year, millions of infants are born to women who did not receive early prenatal care.

- In 1988, about one in four babies nationwide was born to a mother who did not benefit from early care.6
- In that year, only 69 percent of all births occurred among mothers whose prenatal care could be considered adequate, even in terms of timing and frequency of visits.
- That year marked the ninth in a row in which the trend in receipt of late (beginning after the sixth month) or no prenatal care worsened or showed no improvement. In 1988, nearly 73,000 infants were born without benefit of any prenatal care.

Comprehensive primary and preventive care for children can detect and treat a wide range of health conditions before they become serious. After birth and throughout childhood, all children need primary care, including regular well-child examinations, immunizations, and care for a minor and acute problems (such as strep throat or ear infections). In addition, some children need specialized follow-up care for detected health problems. In particular, regular check-ups for problems such as lead poisoning, learning disabilities, vision impairments, and dental health needs can reduce the consequences of these health problems. Children who receive comprehensive primary health care have annual health costs 7 to 10 percent lower than those who do not. However, national survey data indicate that many children, particularly those in low income families, do not receive the basic primary care needed by every child.

- In 1988, among children younger than 18 living in affluent families (with annual family incomes greater than $35,000), one in seven had no physician contact in a year, compared to one in five poor children (with family incomes less than $10,000). 7
- Poor children were at least 3 times more likely than affluent children never to have had a physician visit.
- Data from 1986 reveal that the poorest children ages 5 to 11 were nearly four times as likely as affluent children of that age never to have had a visit to a dentist.8

The Role of Insurance in Ensuring Access to Care

Studies have shown that health insurance is a significant factor in families' decisions about how and when to use health care. Uninsured children and pregnant women use substantially fewer services than their insured counterparts, even when the need for services is taken into account.[9]

- Uninsured low income women are less likely to receive care early in pregnancy and are twice as likely to receive late or no prenatal care than women with private health insurance. 10
- The Institute of Medicine of the National Academy of Sciences reports that: "financial barriers--particularly inadequate or no insurance and limited personal funds--were the most important obstacles reported in 15 studies of women who received insufficient care." 11
- Low-income uninsured children have a lower likelihood of having any visits and a significantly lower average number of visits to physicians, even after adjustments for health status. 12
- Among children with identified disabilities who participate in special education programs, lack of health insurance has been found to be associated with reduced access to necessary health care. 13

However, research also has shown that, even among the poorest families, adequate health care coverage can bring health care utilization up to levels found among well insured, non-poor children. In particular, poor children with Medicaid coverage are far more likely than uninsured poor children to have a regular source of health care, visit a physician in a year, and receive preventive services.[14]

The Inadequacy of Current Insurance Coverage

As a result of reductions in dependent coverage under employer-based health insurance plans and reductions in federal and state public insurance programs for low-income children during the early 1980s, the proportion of uninsured children grew by more than 15 percent. As a group, children are especially likely to be uninsured -- representing approximately 30 percent of the 33 million uninsured Americans under age 65 in 1988.[15] Women of childbearing age, including workers or dependents of workers, also face an increased risk of being without health coverage. In 1986, more than 9 million women ages 15 to 44 were completely uninsured.

Low income families, who generally lack the means to pay for health care expenses "out-of-pocket," are among those most likely to be uninsured.

- Between 1980 and 1985, the proportion of children under age 18 covered by employer insurance fell by 6 percent (from 64.6 percent to 60.6 percent). Among poor children under age 18, the proportion privately insured declined by one-quarter, from 16.9 percent to 12.8 percent. 16
- By 1988 nearly one-third of all poor children were uninsured. Despite recent Medicaid expansions covering all children under age 6 with family incomes below 133% of the federal poverty level, an estimated 2.5 to 3 million poor children ages 6 to 17 remain without health insurance. 17
- While recent federal changes in Medicaid effective April 1, 1990 assure coverage of all pregnant women with family incomes up to 133 percent of the federal poverty level (about $14,000 per year for a family of three), an estimated 75,000 near-poor women (with family incomes between 133 and 185 percent of poverty) continue to be uninsured. 18

3. WHAT REFORMS ARE NEEDED TO IMPROVE THE ADEQUACY OF MEDICAID COVERAGE FOR LOW INCOME FAMILIES, ESPECIALLY CHILDREN?

In recent years, Congress has taken steps to improve access to health care for pregnant women, infants, and children. These preventive investments include changes in key maternal and child health programs such as Medicaid, the Maternal and Child Health Block Grant, Community and Migrant Health Centers, childhood immunization, and health personnel programs.

The Medicaid program is the primary health care financing program for low income children and pregnant women.

- In 1987, Medicaid paid for maternity care for approximately one-half million births that year -- nearly one in every six U.S. births. 18

- In 1989, nearly 11.5 million children under age 18 received services paid for by Medicaid. 19 While children comprise not quite half (49 percent) of all Medicaid recipients, but account for only about 15 percent of total expenditures. The average monthly cost of Medicaid assistance for a child is about $80--less than it costs to purchase a monthly parking space in most Capitol Hill area garages.

Because of the importance of adequate health care coverage and the size and scope of the program, changes in the Medicaid program are among the most significant of the maternal and child health policy reforms made during the 1980s. As a result of Medicaid improvements enacted by Congress since 1984:

- Some 200,000 additional pregnant women, and a million more infants and children younger than six with family incomes below 133 percent of the federal poverty level are now covered.

- More than 15 states now have extended coverage to pregnant women and infants with family incomes below 185 percent of the federal poverty level (roughly $18,000 per year for a family of three).

Despite recent improvements, however, the Medicaid program continues to fall far short of fulfilling its mission to address the health care needs of poor Americans. For example:

- Federal eligibility rules currently do not allow coverage of poor children older than age 7 with family incomes above state AFDC or medically needy financial eligibility levels, (on average these standards leave older children's coverage at 50 percent of the federal poverty level).

- Even eligible women and children find the application process so difficult that in some states as much as 50 percent of applicants are denied not because they are ineligible but because of failure to comply with complex procedures.20

Steps should be taken this year to further improve Medicaid's ability to serve low income children and pregnant women, as well as other vulnerable groups. If the nation is to make real progress toward reducing infant and childhood death and disability, then the reform efforts undertaken since the mid-1980's must be expanded and strengthened.

Pending Legislation

- **The Medicaid program should be expanded to cover all poor children.** Legislation designed to phase-in mandatory coverage of poor children over the next 10 years and permit states to extend such coverage immediately (H.R. 3932) has been introduced by Representatives Jim Slattery (D-KS), Henry Waxman (D-CA), and others. This bill also would require outreach locations, improve pediatric hospital reimbursements and encourage states to cover all poor children in foster care.
- **Medicaid coverage should be provided to all pregnant women and infants with family incomes below 185 percent of the federal poverty level.** Bi-partisan legislation (H.R. 3931) has been introduced by Representatives Cardiss Collins (D-IL), Henry Waxman (D-CA), Hyde (R-IL), and others to phase-in such coverage, ensure expedited eligibility determination procedures, and improve home visitor benefits.
- **Federal funding should be provided to permit states to improve their Medicaid programs in a number of additional ways.** For example, H.R. 5480, introduced by Representative Durbin (D-IL) and others, would require states to provide continuous coverage to eligible pregnant women and infants, allow states to provide annual enrollment periods for children, and create new community-based outreach programs.
- **Medicaid drug treatment for families** also should be a priority. The Medicaid Drug Treatment for Families Act, H.R. 5536 as introduced by Representative Towns, would give states the option to cover comprehensive residential alcohol and drug treatment services to pregnant women and women with young children. Current law precludes coverage for all non-hospital residential drug treatment programs.

> As the White House Task Force on Infant Mortality found in its November 1989 report, the exceedingly great need for such residential treatment services is demonstrated by the high number of infants born each year to women who have abused alcohol or drugs. This legislation would make possible comprehensive service programs for such women and their children, which have been found effective in reducing the damage caused by alcohol and drugs. Such programs represent a cost-effective alternative to the already overwhelmed foster care and criminal justice systems.

We strongly support all of these measures and hope that this Committee will adopt them in their entirety.

Additional Technical Clarifications and Improvements

We also request that the Committee include in its legislation several small but important changes in Medicaid that would considerably improve and strengthen its performance for women and children.

1. Medicaid Eligibility for Migrant Farmworker Families

Among all populations potentially eligible for Medicaid but not enrolled, migrant farmworker family members rank among the most vulnerable. The patient population served by the nation's more than 125 federally funded migrant health centers centers is overwhelmingly comprised of young families with women of childbearing age and young children. Yet a distressingly small proportion of eligible women and children is enrolled in Medicaid. This lack of Medicaid coverage of eligible migrant family members has an enormous impact on patients' access to essential services and on the service capacity of the migrant health centers themselves, since centers' federal grants underwrite less than half their operating costs.

The chief cause of eligible migrant family members' lack of Medicaid coverage is their mobility. Because Medicaid is a state-based program, persons whose residence changes frequently have a difficult time either attaining or maintaining coverage. In the case of migrant families, this difficulty arises from their need to move frequently for employment related reasons.

In 1979 HCFA attempted to remedy the problem of migrants' inability to qualify for Medicaid by promulgating regulations which permit migrants to treat their state of residence for employment purposes as their state of residence for Medicaid eligibility purposes. 42 CFR 403 (i). But these rules had little practical impact on migrants' receipt of the medical assistance to which they are entitled. Migrant families frequently do not remain in one state long enough to take advantage of employment-related coverage. For example, federal rules permit states to take up to 45 days to determine eligibility for non-disabled applicants. By the time the process is complete, migrant women and children often have moved on. Even those who have time to complete the lengthy application process rarely get to use benefits.

For those migrant families who elect to apply for coverage in their state of permanent residence and to then travel with a valid out-of-state card, problems are equally serious. Federal regulations governing payment for services rendered on an out-of-state basis limit coverage to emergency or urgently needed services, unless it can be demonstrated that it is the common or preferred medical practice to seek care on an out-of-state basis 42 CFR 431.52. While out-of-state care is indeed common for migrant workers, state Medicaid systems have no practical way of distinguishing a non-emergency out-of-state bill for a migrant worker from one submitted on behalf of a non-migrant beneficiary who happens to obtain care out-of-state, even though in this case it would not be customary practice to do so. Therefore, such coverage commonly may be denied.

Moreover, migrant workers traveling on an interstate basis with out-of-state Medicaid coverage face the added problem of finding providers willing to accept out-of-state patients. For migrants who are served by migrant health centers, this obviously is not a problem. But out-of-state coverage poses an enormous barrier in those situations in which either no health center is close by or the patient needs care and services not furnished by the center.

Under current federal regulations, states may enter into interstate residency agreements to facilitate coverage of, and payment for, services rendered to out-of-state residents. 42 CFR 403 (k). However, these agreements potentially are limited by the scope of the statute itself. Thus, for example, it is unlikely that Georgia could, through an interstate agreement with Florida, agree to automatically treat as in-state residents all pregnant migrant women with a Florida coverage, since Florida's eligibility standards for pregnant women are more generous than those used in Georgia. Treating pregnant beneficiaries from Florida as Georgia beneficiaries without redetermining eligibility potentially could lead Georgia to provide assistance benefits to a woman whose family income exceeds allowable levels under its state plan. Therefore, while states clearly can use their interstate compact authority to enter into reciprocal payment arrangements where interstate eligibility criteria are identical (for example, in the case of Title IV-E children or for SSI-recipient residents of long-term care institutions), such an arrangement would raise potential legal problems when eligibility criteria vary (no matter how slightly) from state to state as in the case of pregnant women, infants and children ages six to twenty-one.

We believe that this barrier to state efforts to remedy the problem can be reduced by amending the statute to permit states to develop special interstate compacts for eligible migrant works. Such compacts would allow states that are parties to a compact to deem as in-state residents migrant workers who have coverage under any plans of a state that is a party to the compact. The authority to treat Medicaid covered migrant family members as in-state residents should be extended to all potentially eligible categories of migrant workers, but states also could be given the authority to limit their agreements to certain categories of beneficiaries.

In order to accomplish this change we believe that both the eligibility and residency provisions of the statute need to be modified as follows:

New optional coverage of deemed migrant workers

Section 1902 (a)(10)(A)(ii) is amended by adding at the end thereof the following new subsection (xii):

> "persons who are eligible for or receiving medical assistance from any state under categories enumerated under Sections 1902(a)(10)(A)(i) or (ii) of the Act, who are migrant agricultural workers (or the spouse or child of a migrant agricultural worker) as defined at Section 329(a)(2) of the Public Health Service Act, and who are deemed as recipients covered under the State plan pursuant to an interstate agreement described in Section 1902(b)."

Extended authority to enter into interstate agreements for coverage of migratory agricultural workers.

Section 1902(b) is amended by adding at the end thereof the following new provision:

> "At its option, a State may enter into an agreement with any other state (or States) under which each State that is party to such an agreement will treat, as a recipient of medical assistance under its plan, one or more categories of persons receiving medical assistance from any State which is a party to the agreement and who are described in in Section 1902 (a)(10)(A)(ii)(XII), regardless of whether, in the absence of such an agreement, such individual or individuals would otherwise be eligible for assistance from the state. Any individual covered by the agreement shall be treated as a resident of the state in which the beneficiary is residing either indefinitely or for employment related purposes."

Finally, in order to reduce the possibility that migrant workers' eligibility will expire during travel periods, we recommend that Section 1902 (e) be amended to permit states with interstate compacts for deemed migrant workers to use up to a 12-month eligibility period for such workers under which coverage is guaranteed regardless of any change in income or resources.

2. Coverage of Pregnant Undocumented Spouses and Undocumented Poor Children

In 1986 Congress amended the Medicaid statute to limit the provision of medical assistance (except in the care of emergencies) to persons who are not U.S. citizens, aliens admitted as permanent residents, or permanently residing under color of law. Section 9529, Pub. L. 99-272. These amendments have virtually eliminated Medicaid coverage for routine non-emergency maternity care for otherwise qualified undocumented women whose children, once born, will be eligible for full coverage as U.S. citizens. The amendments also eliminate all but emergency services for otherwise eligible children who are undocumented.

We believe that this policy has severe human and financial consequences for women and children and states. Especially in the case of pregnant women, the 1986 amendments all but guarantee that the children born to undocumented women (and a state Medicaid program) will face a heightened risk of death or disability and that state agencies will incur extraordinary medical bills for infant conditions that could have been averted through comprehensive maternity care.

While we would like to see these limitations reversed entirely, we are mindful that this is not possible at the present time. However, we do recommend that the Committee modify the current prohibition to permit States to extend full Medicaid coverage in the case of undocumented pregnant women or children who are otherwise eligible under Sections 1902(a)(10)(A) of the Act and who satisfy the requirements of the Family Fairness Doctrine developed by the Immigration and Naturalization Service (INS). This doctrine grants permanent legal status for undocumented spouses and children under age 18 of lawfully present aliens so long as the spouse and children can demonstrate that they are:

- are the spouse or minor child of a lawfully resident alien;
- reside with the alien;
- have not been convicted of a felony or three misdemeanors committed in the United States; and
- have not assisted in the persecution of any person on the grounds of race, religion, nationality, membership in a particular social group or political opinion.

Because establishment of lawful status under the Family Fairness Doctrine can take considerable time, and because the need for maternity or pediatric care is pressing, we recommend that the statute be amended to permit State Medicaid agencies to grant coverage for Medicaid purposes only to otherwise eligible spouses and children who can satisfy the requirements of the Doctrine, regardless of whether an application for voluntary departure under the doctrine has been submitted to INS.

3. Federally Qualified Health Centers

In 1989 Congress amended the Medicaid statute to add as a required benefit the services of federally qualified health centers (FQHCs) and to require that such providers be reimbursed for the reasonable cost of furnishing covered services. Pub. L. 101 - 239, Section 6402. FQHC services include (at a minimum) services offered by health centers funded under Sections 329, 330, and 340 of the Public Health Service Act whose coverage is either required when furnished by a rural health clinic or else is covered as an ambulatory service under a state Medicaid plan. Section 1905 (a)(2)(c). Reasonable cost reimbursement must be paid to FQHCs for required services furnished, as well as all for all other ambulatory care furnished which is covered under the state Medicaid plan. Section 1902 (a)(13)(e).

The purpose of these amendments was to assure that, as in the case of hospitals serving a high volume of low income patients, providers of primary health services who furnish care to large numbers of low income patients, whose revenues are otherwise severely limited, and who receive or satisfy the requirements of Sections 329, 330, or 340 of the Public Health Service Act, are assured recovery from Medicaid of at least the cost of care and services furnished. These amendments were designed to ensure that FQHCs are not forced to use their scarce grant revenues, intended to meet the needs of medically indigent uninsured persons, to compensate for the shortfall caused by excessively low Medicaid reimbursement.

The nation's federally funded community and migrant health centers and homeless health care clinics, which have been assisted by this change in the law, provide more than 10 percent of all maternity care to low income women nationally, more than 30 percent of the maternity care furnished to women under the age of 15, and serve more than 3 million poor children. They are a vital source of decent quality, comprehensive primary care for the communities they serve. Half of the patients served by these providers have no health insurance, public or private.

Generally states have implemented the FQHC program swiftly and with reasonable precision. States are to be commended for their efforts, since HCFA to date has issued only very limited, informal guidance to assist them in their implementation efforts. However, several problems have arisen, one of which threatens to undo the reforms in many states.

a. Facilities qualifying for FQHC reimbursement

One issue which has arisen concerns which types of federally funded facilities qualify as FQHCs. The law defines FQHC services as those offered by "a health center that receiving funds under section 329, 330, or 340 of the Public Health Service Act...." Section 1905 (a)(2). The Bureau of Health Care Delivery Assistance, (BCHDA) the arm of the Public Health Service which administers the 329, 330, and 340 programs, makes grants to two distinct types of "centers." In one case the grant goes to an entity in which the body receiving and administering the grant and the body that furnishes the care and services are one and the same. In other cases, because of state law or for other reasons, the "center" is comprised of two distinct entities: a community-board controlled entity that receives the grant and administers the program; and a medical group practice that contracts with the corporate entity but which is subject to the control of the consumer board corporate entity. For example, since Texas law prohibits physicians from being employed by health care corporations, Texas health centers technically exist as two separate entities. One entity, with its corporate board, is technically 330 grantee and thus controls the terms and conditions of the 330 grant. The physician entity in turn contracts with the recipient entity to practice in accordance with the grant recipient's terms and conditions.

Both types of "health centers" -- those which exist as single entities and those with "dual" status are 329/330 recipients and are treated as community health centers by BCHDA. Yet HCFA has ruled that these dual entities are not "health centers". The effect of this ruling, that a health center can qualify as a "health center" only if the grantee and the service provider are the same, has the effect of denying FQHC status to Section 330 grantees all over the country. Without such status, these grantees will continue to be forced to use federal grant funding intended for uninsured patients to subsidize extremely low Medicaid reimbursement rates and will not realize the benefits of the 1989 amendments. We therefore ask that the term "health center" be defined to include both those entities which both receive the grant and provide the service, as well as dual entities.

b. EPSDT and FQHCs

A recent ruling from the Office of General Counsel (attached to this testimony) holds that, in determining the cost-based reimbursement rate for FQHCs, states have the option to exclude from centers' cost-based the rate those EPSDT screening, diagnosis, and treatment services that are not also required FQHC services under Sections 1905 (a) and 1861 (aa) of the Act. The Office of General Counsel specifically indicates that this position is being taken in order to "limit" the scope of the ambulatory service requirement under the FQHC statute.

This ruling is incomprehensible. It flies directly in the face of the statute, which requires that FQHCs receive cost based reimbursement both for required FQHC services and for all other ambulatory services furnished. Section 1902 (a)(13)(E). It will severely depress the potential revenue that health centers otherwise would receive if they were to expand or enrich their services to include non-required ambulatory care services for children whose EPSDT screenings (either periodic or interperiodic) disclose a problem. The net result certainly will be diminished ambulatory services for children living in severely medically underserved areas. We therefore ask that Section 1902 (a)(13) be amended to clarify that all services which are required for EPSDT children under Section 1905 (a)(2)(c) of the Act and that also fall within the definition of FQHC services under Section 1905 (a)(2)(c) of the Act must be reimbursed in accordance with the principles enumerated under

Section 1902 (a)(13)(e).

c. Managed Care Plans

A significant number of states currently contract with HMOs or primary care case managed care systems to furnish services to Medicaid beneficiaries. These networks may be paid substantially less than cost for the care and services they furnish. A recent HCFA ruling has held that because health centers, according to HCFA, are free to not participate in an HMO or managed care arrangement if the rates are not sufficient, it is therefore permissible for states to allow HMOs to exclude health centers from the plan or network if they do not accept the reduced rate. By implication, states also would be free to use their Section 1915 authority to establish primary case managed care plans that require health centers to accept, as a condition of remaining Medicaid providers, less than the cost based reimbursement to which they are entitled. Because so many community health centers are located in areas in which these plans are in operation, this ruling has the potential to completely unravel the 1989 amendments. We ask that it be reversed.

FQHC services are a required service, and the reimbursement methodology covering both FQHC and other ambulatory services is a mandatory one. These mandates were added to aid health centers serving the uninsured. Health centers that participate in managed care plans also see high numbers of uninsured patients. For both legal and policy reasons, state Medicaid agencies should not be free to force health centers (either directly or indirectly) to either accept discounted payment rates under an HMO or Section 1915 managed care arrangement or forego Medicaid reimbursement entirely.

Legally, General Counsel's ruling is simply wrong. To suggest, as it does, that health centers are "voluntary" negotiators with either HMOs or state Medicaid agencies is incorrect. By law, health centers are obligated to participate in Medicaid. 42 USC Section 254 C Thus, centers that are offered less than cost based reimbursement by their plan contractor have no recourse but to remain in the Medicaid program at a reduced, payment rate. Centers that reject the rate offered them risk the loss of not only Medicaid revenues but their Public Health Service grants, as well because of non-compliance with the Medicaid participation requirements of the Act.

From a policy point of view, HCFA Office of General Council's ruling is wrong, as well. Without health centers, millions of uninsured patients would have no adequate source of care at all. The federal grants supporting health centers are sufficient to underwrite only half of their operating costs. Without Medicaid, scores of centers would vanish. It is essential that health centers not be forced to forego the cost based reimbursement to which they are otherwise entitled in order to participate in a managed care plan. We therefore recommend that the statute be amended to clarify that :

o Section 1905 (a)(2)(c) and 1902 (a)(13)(e) are non-waivable requirements under Section 1915(b) of the Act. States using Section 1915 arrangements must utilize FQHCs in their plans and must supplement payments made to health centers under the plan when such payments otherwise fall short of centers' reasonable cost.

- The FQHC service coverage and reimbursement requirements are a condition for all Section 1903(m) plans. As with Section 1915(b) plans, HMOs that sub-contract with FQHCs can either pay cost and be compensated by the state or else the state can directly make FQHCs "whole" through a supplemental reimbursement. The state of Wisconsin in fact has just entered into such a supplementation arrangement with its health centers that are part of a prepaid managed care plan. HMOs that are themselves FQHCs must be assured of capitated reimbursement equal to 100 percent of their reasonable costs.

d. Calculation of the FQHC Rate

Finally, we seek clarification that, in calculating the rate that is to be paid to an FQHC, states exclude the 329, 330 or 340 grant from their cost calculations. Some agencies currently are subtracting centers' Public Health Service grants in calculating health centers' uncovered costs. In doing so, these agencies are engaging in exactly the practice which Congress sought to prohibit -- paying centers only for that share of patient care cost not borne by their Public Health Service grants. The FQHC amendments were designed to assure that in the case of Medicaid recipients, FQHCs do not rely on their grants to carry the cost of furnishing covered care and services, so that such grants might be reserved for uninsured patients.

4. Medicaid Payment for Childhood Vaccines

This year Congress may consider changes in the structure of Medicaid payments for prescription drugs. One proposal would provide for an entirely restructured system under which reduced prices for prescription drugs for Medicaid recipients. The bill proposes use of a competitive bidding approach and use of "therapeutic equivalent" pharmaceuticals that could be provided at the lower cost. One major alternative to this approach, developing a price rebate system, has been proposed by several pharmaceutical manufacturers. As currently discussed, either of these reforms might inadvertently sweep vaccine products into the new system. We believe that this would be a mistake and urge the Committee to give special attention to the treatment of vaccines while pharmaceutical product prices are being considered.

The central reason vaccine products should be exempt from any amendments related to prescription drugs is that they are not delivered in the manner traditional for prescription drugs. In general, Medicaid agencies to not set the reimbursement for vaccines based on the actual price per dose. Rather, Medicaid agencies most often set a provider reimbursement rate that for a visit for immunization services. In some cases, this rate is set for an overall well-child visit and not specific rate is established for vaccines. In any case, rarely does Medicaid reimburse directly for the cost of an individual vaccine.

A second reason for special treatment of Medicaid reimbursement for vaccines is the fact that the nation already has a bulk purchase program for vaccines. Under Section 317 of the Public Health Service (PHS) Act, the Centers for Disease Control has authority to maintain a national bulk purchase system for vaccines. The federal funds in this grant program are sufficient to purchase one-quarter of all vaccines administered to children each year. (Another quarter is publicly purchased with state dollars, and the remaining half is privately purchased.) It also is important to note that the public sector, bulk purchase price currently is about one half of the private sector price.

In addition, the nation's vaccine purchase system is made even more complex by the National Vaccine Injury Compensation System. Pub.L. 99-660 and 100-203. This "no fault" system for providing compensation in the cases of an injury resulting from routine immunization is primarily financed through an excise tax on vaccines that goes into a trust fund for vaccine compensation. Because the market price of a dose of measles, mumps, rubella, diphtheria, tetanus, pertussis, or polio vaccine includes the excise tax, it would be difficult to structure a rebate or other discount price system.

We hope that states will take action to set fair prices for the delivery of childhood immunizations -- to cover the vaccine cost and cost of administering the vaccine. Adequate payment for publicly funded clinics and for private physicians are essential to ensuring an adequate supply of immunization providers. In addition, Medicaid agencies should enter into interagency agreements with state health agencies to ensure that Medicaid providers are receiving vaccines through the existing bulk purchase system whenever possible. The lagging immunization rates among low income infants and toddlers is a national disgrace, and every Medicaid recipient child should be appropriately immunized.

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① OGC ruling

APR 20 1990

NOTE TO BILL HICKMAN

Re: Section 6404 of OBRA 89 -- Federally-qualified Health Centers (FQA-723)

This responds to Kathy Buto's April 2, 1990 memorandum on the captioned subject. That memorandum raises three sets of questions about the Federally-qualified health center (FQHC) services benefit package enacted by the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), Pub. L. No. 101-239. Section 6404 of that legislation amended the Medicaid statute to provide coverage of these benefits under a new section 1905(a)(2)(C). Inclusion of the benefit is mandatory for the categorically needy. *See* § 1902(a)(10)(A). The amendments apply to calendar quarters beginning April 1, 1990. OBRA 89, § 6404(d).

Section 1905(a)(2)(C) describes the FQHC services benefit package as consisting of "Federally-qualified health center services as defined in [section 1905](*l*)(2)," and "any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan." Under section 1905(*l*)(2)(A),[1] "Federally-qualified health center services" are delineated in terms of Medicare rural health clinic services, that is, "services of the type described in [section 1861(aa)(1)(A)-(C) of the Medicare statute] when furnished to an individual as an outpatient of a Federally-qualified health center . . ." The statute provides that a "Federally-qualified health center" is a grantee under sections 329 (migrant health centers), 330 (community health centers), or 340 (health center services for the homeless) of the Public Health Service (PHS) Act or an entity which has been determined by the Department to meet the requisites for such grants. Section 1905(*l*)(2)(B).

HCFA asks, first, whether any entity which receives a grant under sections 329, 330, or 340 of the PHS Act must automatically be considered an FQHC if it provides services to Medicaid recipients, or whether the facility has a choice of becoming such an entity. The statute does not contemplate affirmative action on the part of such PHS grantees to become FQHCs. Those facilities are automatically treated as FQHCs for purposes of

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[1] This language, and that in subparagraph (B), was enacted in subsection 6404(b).

Prepared by: OGC/HCF:SFRANCIS:mlr:13/FQHC:4/19/90
Control No: 8288
Subject: MEDICAID COVERAGE -- GENERAL

reimbursing FQHC services under Medicaid as long as they remain in the designated PHS grantee status.[2] In addition, non-grantee entities would be entitled to be considered FQHCs if the PHS Health Resources and Services Administration determines they meet the requirement for such grants.[3] § 1905(l)(2)(B). Thus, we would characterize the nature of the FQHC somewhat differently than the April 2 memorandum does, and would not say that an entity becomes an FQHC upon serving Medicaid beneficiaries or seeking payment. Rather, if an entity is a section 329, 330 or 340 grantee, or has been appropriately determined to meet the requisites for becoming such a grantee, it is an FQHC for Medicaid reimbursement purposes, and the State can seek Medicaid reimbursement for section 1905(a)(2)(C) services the entity provides to Medicaid-eligible individuals under the State's plan.

We do not think the States have the authority to determine the payment methodology for "FQHC services." The statute mandates the rate of payment. Section 1902(a)(13)(E), amended by subsection (c) of section 6404, provides that the State plan must reimburse FQHC services based on 100% of the reasonable costs of providing the services or other tests of reasonableness prescribed by the Secretary in regulations under section 1833(a)(3) of the Medicare statute. This is distinct, however, from requiring that all payments to an FQHC be made at 100% of reasonable costs. The amendments do not do that; the rate of payment States make for services provided by an FQHC other than those included in the FQHC services benefit package are not affected by these provisions.

Second, HCFA asks for guidance in defining, and limiting the meaning of "ambulatory" in section 1905(a)(2)(C) and suggests, in particular, that it would be appropriate to give States latitude in determining what ambulatory means as it applies to EPSDT services provided by an FQHC. In order to offer guidance on the scope of "ambulatory," we would need at least some policy parameters from HCFA. We can offer several preliminary observations, however. If HCFA wishes to define "ambulatory," particularly if its definition would constitute a limit on services, it must do so through the notice-and-comment rulemaking process. HCFA could leave the definition to the States, if it chooses, but that discretion should be limited by a requirement that States use the same definition of ambulatory they use for other Medicaid services, e.g., section 1902(a)(10)(C)(iii). The statute vests no greater or lesser degree of discretion in the

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[2] This conclusion does not require these facilities to furnish services under Medicaid, however.

[3] It is not clear entitlement could occur without affirmative action by facilities seeking this status.

States to define "ambulatory" in terms of the EPSDT benefit than for any other Medicaid benefit. The same meaning developed for "ambulatory" for purposes of other Medicaid services incorporated by section 1905(a)(2)(C) must apply to determine the scope of services required under EPSDT.

We assume that HCFA's concern about the EPSDT implications of the FQHC legislation arises from the language of section 1905(r)(5) of the Medicaid statute, also enacted in OBRA 89 § 6404. Section 1905(r)(5) defines the EPSDT benefit to include screening, hearing, vision, and dental services, and:

> Such other necessary health care, diagnostic services, treatment and other measures, as described in section 1905(a), to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan.

(Emphasis added.) While sections 1905(a)(2)(C) and 1905(r)(5), read together, produce, in part, a conflicting, and absurd, result,[4] we think a reasonable reading is available which would accord both sections full meaning. In doing so, section 1905(a)(2)(C) should be read to take precedence over section 1905(r)(5), for several reasons. That course allows the FQHC benefit package to have clear generally understood boundaries. While Congress defined FQHC services in part (in terms of Medicare rural health clinic services), it did not give an established, prophylactic contour to the benefit; it left part of the definition to the States to some extent by causing the term to embrace "other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan." (Emphases added.) The emphasized phrase is thus fundamental to the definition of the FQHC services benefit package, and clearly is necessary for closure of the definition.[5] Moreover, the FQHC benefit is the more specific and narrow of the two provisions, and, in accordance with traditional rules of interpretation, should, consequently, take precedence over the more general section 1905(r)(5).

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[4] Read with section 1905(r)(5), section 1905(a)2)(C) would effectively state that the FQHC services benefit includes any other ambulatory services offered by an FQHC "which are otherwise included in the plan whether or not such services are covered under the State plan."

[5] Of course, section 1905(r)(5) itself lacks a closed definition, but that is inherent in the provision itself, and not the result of its interplay with section 1902(a)(2)(C).

Read in the way we have suggested, if a State finds it necessary under section 1905(r)(5) to provide the FQHC services benefit to an EPSDT recipient, it must offer the recipient any needed services in that benefit package. That package would consist of "FQHC services," that is, prescribed rural health clinic-type services, plus any other ambulatory services specifically covered under the State plan.

The construction we suggest does not eclipse the EPSDT services to which a beneficiary is entitled under section 1905(r)(5). It simply permits the State to place appropriate controls on the category into which such services fall. For example, assume that an EPSDT child is found to require physical therapy services and that they are not covered under the State's Medicaid plan. Assume, further, that physical therapy services do not meet the definition of FQHC services, but that they are ambulatory services and that FQHCs in the State do offer them. Under the construction we have suggested, the State must provide the EPSDT child with physical therapy services. However, it would not be required to provide them as "FQHC services." This result could be significant in terms of reimbursement. As we have discussed above, section 1902(a)(13)(E) requires reimbursement of services included in the section 1905(a)(2)(C) benefit at 100% of reasonable cost, whereas different reimbursement schemes might apply to some other services provided under the plan. If the EPSDT provision were to given precedence, the effect could be to compel the States to provide virtually any service they are mandated to offer by section 1905(r)(5) in the form of a section 1905(a)(2)(C) service (assuming the FQHC offered it), payable at the FQHC rate, a result clearly not intended by Congress.

This interpretation also satisfies the traditional canons of statutory construction, which require that when two provisions apply, both must be accorded a reasonable meaning, if it is possible to do so, and no part may be rendered surplusage. It gives greater weight to the more specific of the two provisions, in this case, the FQHC benefit.[6]

Third, HCFA asks whether a State must cover "clinical psychologist and clinical social worker services" as part of the FQHC services benefit package even though they are not covered in the State plan. The response to that question depends upon whether these services are "of the type described in [section 1861aa(1)(A)-(C) of the Medicare statute]," the standard set in the first prong of section 1905(1)(2)(A). Subsections (A)-(C) specify physicians, physicians' assistants, and nurse practitioner services, and certain "incident to" services and supplies; neither they nor HCFA regulations defining rural health clinic services, 42 C.F.R. § 410.45, mention the services of clinical psychologists or clinical social workers. However, if HCFA covers such services as rural health clinic services, or if it considers them to be ambulatory services and they are otherwise included in the State plan, they cannot be excluded from the section 1905(a)(2)(C) benefit package.

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[6] Because both subsections were enacted in the same legislation, the principle that the later-enacted provision takes precedence over the earlier does not come into play.

Please let us know if we can be of further help.

Sarah Wilcox Francis
Senior Coordinating Attorney

cc: Kathy Buto
Bob Wren

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

REFER TO: FQA-723

② Buto Request

Memorandum

~~Ed~~ Francis
#2

due 4/11/90

Date APR 2 1990

From Director
Bureau of Policy Development

Subject Section 6404 of OBRA-89 - Federally Qualified Health Centers (FQHCs)

To Office of the General Counsel

We are requesting guidance on certain issues concerning the FQHC benefit. For background, we have attached a copy of sections 4231 and 6303 of the State Medicaid Manual. These are new instructions which have cleared the Administrator's office (with a request by the Office of Issuances that they be distributed by 3/29). The questions are:

1. Must any entity which receives a grant under section 329,330, or 340 of the PHS Act be automatically qualified as an FQHC if it provides services to Medicaid recipients? Does such a facility have a choice in this matter? Does the State agency have any flexibility in deciding how it would pay for services in such situations? We believe that a grant receiving entity automatically becomes an FQHC if it serves and seeks payment for medical care provided to Medicaid recipients. However, we have recently learned that some States have been paying for services provided by Community Health Centers (330 grantees) on a basis other than what will be required under the FQHC benefit, and may want to continue that method after April 1, the effective date for the FQHC benefit. We are hoping to be able to answer this question before it becomes a controversial issue.

2. Section 6404 of OBRA-89, when defining FQHC services, included "any other ambulatory services offered by a [FQHC] and which are otherwise included in the plan". Please provide guidance as to how to define, and possibly to limit, the meaning of "ambulatory" in the FQHC benefit. We believe it would be appropriate to give States latitude in determining what ambulatory means as it may apply to EPSDT services provided by an FQHC.

3. May a State exclude clinical psychologist and clinical social worker services from the FQHC benefit? FQHC services are defined as "the type described in subparagraphs (A) through (C) of section 1861 (aa)(1)" of the Act (section 6404(b)(3) of OBRA-89), and as "any other ambulatory services

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offered by an [FQHC] and which are otherwise included in the plan" (section 6404(a)(3) of OBRA-89). Does the phrase "otherwise included in the plan" permit a State to exclude psychologist and social worker services provided by an FQHC if they are not included in the State plan, or does the 1861(aa)(1) reference require a State to pay for the services even though the service is not included in the State plan. We believe that the former interpretation may be the correct one, but we want to be certain we are on legally sufficient ground before we declare it as HCFA policy.

We are seeking initial guidance on [redacted] these three questions that will enable us to assist the regional offices and States as they begin implementing this new benefit. If there are any questions concerning this memorandum, please contact Thomas Saltz at ext. 64641.

Thank you for your timely assistance with our request.

Kathleen A. Buto

Attachment

Children's Defense Fund

122 C Street, N.W.
Washington, D.C. 20001

DEAR LORD
BE GOOD TO ME
THE SEA IS SO
WIDE AND
MY BOAT IS
SO SMALL

Telephone (202) 628-8787

Comments of the Children's Defense Fund on the Medicaid Rulemaking Process

for the Federal Administrative Conference

August 1990

Introduction

The Children's Defense Fund is a national public charity which provides long-range and systemic advocacy on behalf of children, with particular attention paid to the needs of low-income and minority children. For more than fifteen years one of our highest priorities has been improving health care for millions of low-income, uninsured and medically underserved children. Because Medicaid is the largest publicly funded health program for poor children, we are extensively involved in efforts to strengthen and improve the program at both the national and state levels, legislatively and administratively. During periods that the Health Care Financing Administration ("HCFA") has been receptive to beneficiary representatives, we have worked with HCFA to develop policies and rules that best serve the needs of low-income children. During periods when informal discussions were not possible, we have monitored regulatory developments closely and have commented extensively on rules affecting eligibility, benefits, provider reimbursement and methods of administration. We therefore have a historical, experienced perspective on major aspects of the Medicaid rule-making process.

Our comments will describe our experience with HCFA from 1981 to 1989, the same time period covered by the report by Eleanor Kinney. In submitting these comments, we recognize that the problems described in these comments are not the fault of the current Administrator and may very well be addressed by her.

Part One provides detailed case studies of the regulatory path of eight federal legislative changes affecting low-income women and children that Congress made to the Medicaid program. The case studies demonstrate a pattern of gross delay, selective implementation, and the extraordinary politicization of HCFA'S rulemaking process during the 1981-1989 period. Part Two describes the response of the Children's Defense Fund to the draft recommendations of the Federal Administrative Conference.

PART ONE: EIGHT CASE STUDIES OF MEDICAID MATERNAL AND CHILD HEALTH LEGISLATION AND REGULATIONS AFFECTING WOMEN AND CHILDREN

Medicaid rulemaking at HCFA has been characterized by unreasonable delay and selective implementation of legislation, based upon HCFA's political agenda. This politicization has included failure to issue regulations to implement legislation with which HCFA disagreed and which the agency had opposed during the legislative process, as well as the repeated promulgation of unlawful rules in the face of explicit legislation to the contrary.

HCFA's delay in issuing published regulations during the 1980s was the result of hostility toward beneficiaries and a desire to reduce expenditures on services for the poor. It is was not caused by the program's complexity (although we recognize that complexity), agency understaffing, or multiple Congressional changes, as claimed by the Kinney report. Kinney, Rule and Policy Making for the Medicaid Program: A Challenge to Federalism, p. 91.

In addition to unreasonable delay in issuing regulations and responding to public comment, the history of HCFA's Medicaid rulemaking process illustrates a pattern of selective implementation. Quick issuance of regulations or guidance followed enactment of eligibility cutbacks, cost control measures, or other changes detrimental to beneficiaries. Slow, incorrect, rules, or no rules at all were issued to implement legislation expanding coverage or establishing or critical beneficiary protections. Kinney, pp. 59 - 60.

Although Kinney correctly flagged these unacceptable administrative practices, the report fails to address two other vital issues: HCFA's practice of delaying for four to ten years its response to public comments on "interim final" regulations, and HCFA's failure to issue any program guidance or rules whatsoever on a variety of profoundly significant legislative reforms of the Medicaid program over the past decade. For example, difficulties in extending Medicaid eligibility to low-income pregnant minors in need of prenatal care have long plagued the program. In response, in 1988, Congress amended the statute to authorize states to ease the methodology used to calculate income eligibility for families, including those in which a pregnant adolescent resides. Medicare Catastrophic Coverage Act of 1988 (MCCA), Pub.L. No. 100-360, Sec. 302, 102 Stat. 684, 750-04 (codified as amended at 42 U.S.C. sec. 1396a (Supp. 1989)). Yet HCFA has never published any regulations regarding this change, nor has it revised preexisting financial eligibility regulations that prohibit the liberalization of financial eligibility requirements in the case of pregnant minors. In large part due to HCFA's failure to promulgate rules, only two states have opted to apply this new flexibility to benefit pregnant adolescents.

The following eight case studies detail HCFA's serious misuse of the regulatory process.

1. OBRA '81 and the "Medicaid Moratorium"

The story of HCFA's rulemaking in the 1980s began in 1981, with passage of a variety of Medicaid eligibility and benefit reductions in the Omnibus Budget Reconciliation Act of 1981 (OBRA '81), Pub.L. No. 97-35, Secs. 2161-2194, 95 Stat. 357, 803-830 (codified as amended at 42 U.S.C. secs. 1396a, 1396b, and scattered secs. of 42 U.S.C. (1982)). The legislation was enacted in July, 1981. An "Interim Final Rule" was issued only two months later. 46 Fed.Reg. 47,976 (Sept. 30, 1981). This illustrates the speed with which HCFA moves when legislation cuts back on beneficiary rights and has potential to reduce costs.

Moreover, the dangers of publishing rules with no prior comment period are particularly well illustrated by these 1981 rules. Legally, the interim final regulations were wildly off the mark. The 1981 changes enacted by Congress had expressly rejected many of the Reagan Administration's original legislative proposals, such as the imposition of restrictions on the financial criteria states could use in determining eligibility for so-called "medically needy" persons (those with incomes too high to automatically qualify for Medicaid but inadequate to cover the cost of necessary medical care), as well as new authority to eliminate certain categories of children from the program. Even though both proposals were flatly rejected by Congress, HCFA's interim final rules interpreted the amendments as if the Administration's proposed changes had been enacted. Since the rules were published in final form, there was no chance to correct them before they went into effect.

Over the next seven years there ensued a "battle royal" between Congress and HCFA over the lawfulness of HCFA's rules. Legislation to overturn the rules was enacted in 1982. Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA '82), Pub.L. No. 97-248, sec. 137, 96 Stat. 324, 376-81 (codified as amended at 42 U.S.C. secs. 1396a, 1396b (Supp. 1989)). When the agency ignored the changes and refused to rescind or modify its illegal rules, Congress imposed a moratorium on their enforcement. Deficit Reduction Act of 1984 (DEFRA '84), Pub.L. No. 98-369, sec. 2373(c), 98 Stat. 494, 1112 (codified as amended at 42 U.S.C. sec. 1396a note (Supp. 1989)). When the agency sought to evade even this seemingly clear moratorium, Congress passed further restraining legislation in 1987. Medicare and Medicaid Patient Program Protection Act of 1987, Pub.L. No. 100-93, sec. 9, 100 Stat. 680, 695-6 (codified as amended at 42 U.S.C. sec. 1396a note (Supp. 1989)). Nine years and at least three statutes later, the illegal regulations remain on the books, and the agency has yet to replace them with a lawful set of rules.

The history of the Medicaid moratorium illustrates HCFA's insistence on flouting Congressional intent by using rules promulgated without opportunity for prior comment to punish states whose Medicaid programs are not as restrictive as the agency desires (even when the agency's agenda ran contrary to law). HCFA's outrageous and dogged twisting of federal law has itself created the Congressional "micromanagement" about which the agency now so loudly complains.

The moratorium history illustrates the amount of resources and time HCFA has been willing to commit to regulatory efforts to subvert Medicaid's mission to serve the poor. In stark contrast to that mission stands HCFA's utter inaction, as well as grossly delayed action, in the face of the most sweeping program reforms for pregnant women and children since Medicaid's inception.

2. Eligibility Expansions for Pregnant Women and Children - DEFRA '84 and COBRA '85

In a series of incremental program changes beginning in 1984, Congress has expanded Medicaid eligibility to approximately one-half million pregnant women and one million children who previously were ineligible for coverage. See DEFRA '84, Pub.L. No. 98-369, secs. 2361, 2362, 98 Stat. 494, 1104-5 (codified as amended at 42 U.S.C. sec. 1396a (Supp. 1989)) and Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA '85), Pub.L. No. 99-272, secs. 9501, 9511, 9529, 100 Stat. 82, 201-2, 212, 220 (codified as amended at 42 U.S.C. secs. 1396a, 1396d (Supp. 1989)) (1986). These changes, initiated with passage of the Deficit Reduction Act of 1984 (DEFRA '84), represent the most significant expansion of Medicaid for women and children since the program's creation in 1965. They thoroughly revise the criteria and methodologies that are to be applied under this enormously complex program in determining eligibility for perhaps the most vulnerable of America's poor -- pregnant women, infants and young children. The Administration opposed each and every expansion.

DEFRA '84 required states to cover all children born after

September 30, 1983 and under the age of five (regardless of family structure) whose family incomes and resources do not exceed a state's Aid to Families with Dependent Children ("AFDC") financial eligibility standards. DEFRA '84, Pub.L. No. 98-369, sec. 2361(b), 98 Stat. 494, 1104 (codified as amended at 42 U.S.C. sec. 1396d (Supp.1989)). This change extended benefits to thousands of extremely poor children who were previously ineligible solely because they lived in two-parent families (or certain institutions or substitute family arrangements).

In addition, DEFRA '84 extended Medicaid eligibility to two large groups of poor, pregnant women who were otherwise ineligible for AFDC because of the absence of a dependent child: (1) those who would qualify for AFDC after the child was born, because the father is absent, incapacitated or dead; (2) those living with the child's father and who would qualify for the AFDC-Unemployed Parent (AFDC-UP) program once the child was born, whether or not the state was actually operating an AFDC-UP program. Id. DEFRA '84 also provided automatic one-year eligibility after birth for infants born to mothers already receiving Medicaid, as long as the children continue to live with their mothers and their mothers continue to be eligible for assistance. Id., sec. 2362 at 1105. This provision was designed to reduce the possibility that hospitals would deny admission to pregnant Medicaid recipients because their newborn infants' insurance status would be uncertain. Finally, DEFRA '84 added a new mandatory 9-month transitional Medicaid benefit period for certain poor workers losing AFDC benefits who otherwise would have lost their medical assistance as well. Id., sec. 2624 at 1134-5.

With the exception of a separate third party liability provision that cut costs (see discussion under example 4), HCFA did not issue an Notice of Proposed Rulemaking incorporating these important legislative changes until November 1985, over one year after DEFRA '84 was enacted. 50 Fed. Reg. 48,102 (Nov. 21, 1985). Two years later, the agency responded to public comments and issued a final rule. 52 Fed. Reg. 43,063 (Nov. 9, 1987). This was more than three years after passage of the legislation. By this time, Congress had enacted two more rounds of benefit expansions. COBRA '85, Pub.L. No. 99-272, secs. 9501, 9511, 9529, 100 Stat. 82, 201-2, 212, 220 (codified as amended at 42 U.S.C. secs. 1396a, 1396d (Supp.1989)) (1986); Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Pub.L. No. 99-509, secs. 9401, 9407, 100 Stat. 1874, 2050-2, 2058-60 (codified as amended at 42 U.S.C. sec. 1396a, 1396r-1 (Supp.1989).

Continuing the reforms begun by DEFRA '84, Congress incorporated a number of key Medicaid improvements for pregnant women and children into COBRA '85. COBRA '85 mandated coverage of all pregnant women with family income and resources below state AFDC financial eligibility levels, whether or not they met other categorical rules. Other COBRA '85 provisions gave states the option of providing an additional 60 days of post-partum coverage for women whose eligibility was pregnancy-related; permitted states to offer pregnant women an enhanced maternity benefit package; and permitted states immediately to cover all the poor children under five added by DEFRA in lieu of a year-by-year phase-in. The Administration opposed all of these reforms and proposed instead to reduce Medicaid expenditures. COBRA '85 also expanded eligibility for certain children receiving state-funded adoption assistance and foster care maintenance payments. The expansion of coverage for children in state-funded foster care and adoptive placements was expressly added to counter a new and restrictive 1985 informal HCFA interpretation of eligibility for these children which, if not overturned, would have resulted in the termination of Medicaid benefits for potentially thousands of children in state-funded adoptions and foster care placements.

HCFA chose to selectively incorporate only two of these COBRA '85 provisions -- mandatory coverage of pregnant women and eligibility for children under five -- into its 1987 final rule implementing the previous DEFRA '84 provisions. 52 Fed. Reg. 43,063, 43,064-07 (Nov. 9, 1987). Because COBRA '85 was enacted after the 1985 Notice of Proposed Rulemaking for DEFRA '84 was issued, these regulations were published for the first time as final, without any opportunity for public comment. This was true even though there were eighteen months between the COBRA '85 changes and the final rule. Because COBRA '85 was passed in April 1986, and final DEFRA '84 rules were not promulgated until November 1987, HCFA had ample time to promulgate a new Notice of Proposed Rulemaking but chose not to do so. In waiving the rulemaking procedure, HCFA stated:

> We do not believe that any useful purpose would be served by delaying the issuance [of these regulations] to obtain public comment and that such a delay would not be in the best interest of the public. The provisions are self-implementing and are effective regardless of whether or not regulations are issued.

52 Fed. Reg. 43,063, 43,070 (Nov. 9, 1987). The agency also expressed concern that the delay caused by issuing a Notice of Proposed Rulemaking and waiting for comments would cause confusion about program requirements. Id.

HCFA did not publish a Notice of Proposed Rulemaking to implement the other COBRA '85 provisions expanding benefits for poor women and children until February 1989, almost three years after the legislation was enacted. 54 Fed. Reg. 7,798 (Feb. 23, 1989). Moreover, these proposed rules did not implement the provisions expanding coverage for children in state-funded foster care and adoption arrangements. To date, no final rule has been issued.

3. Benefit & Eligibility Expansions for Pregnant Women and Children - OBRA '86 & OBRA '87

Six months after COBRA '85 was enacted, Congress passed a further series of maternal and child health coverage expansions in the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Pub.L. No. 99-509, secs. 9401, 9407, 100 Stat. 1874, 2050-2, 2058-60 (codified as amended at 42 U.S.C. sec. 1396a, 1396r-1 (Supp.1989)). OBRA '86 gave states the option of setting liberalized financial standards for pregnant women and children that included coverage up to the federal poverty level (about twice as generous as state AFDC eligibility levels) and the option to exempt pregnant women and children from a resource test. It also mandated post-partum coverage for pregnant women and gave states the option of guaranteeing eligibility throughout pregnancy, regardless of changes in income. Id., sec. 9401 at 2050-01.

OBRA '86 also provided continuous eligibility for children who reach the Medicaid maximum age limit while they are inpatients in certain hospitals. Id., sec. 9401(d) at 2051. Finally, Congress created the "presumptive eligibility" program, designed to speed the Medicaid application progress for pregnant women in order to promote early prenatal care and reduce infant mortality. Id., sec. 9407 at 2058-60.

Although these Medicaid changes were enacted nearly four years ago, HCFA has never published even a Notice of Proposed Rulemaking to implement them. The agency did act on the presumptive eligibility program by issuing an unpublished Action Transmittal in 1987 adopting a severely restrictive interpretation regarding access to services during the presumptive eligibility period. HCFA's interpretation effectively defeated the very purpose of the presumptive eligibility program -- which was to allow for swift Medicaid enrollment comprehensive prenatal care immediately. Therefore, Congress once again was forced to rein in HCFA by overruling the unpublished HCFA interpretation in the Medicare Catastrophic Coverage Act of 1988 (MCCA '88), Pub.L. No. 100-360, sec. 411(k)(16), 102 Stat. 684, 799 (codified as amended at 42 U.S.C. sec. 1396r-1(d)(1)(B) (Supp.1989)). Once again the agency had gone out of its way to restrict, arbitrarily and without public notice or comment, benefits which it has opposed, and once again Congress had to intervene at an extremely detailed level.

The next round of Medicaid improvements for pregnant women and children was the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Pub.L. No. 100-203, secs. 4101, 101 Stat. 1330, 1330-140 to -143 (codified as amended at 42 U.S.C. sec. 1396a (Supp.1989)). States were given the option of covering pregnant women and infants with incomes under 185 percent of the federal poverty line (more than three times the average state AFDC eligibility level).

OBRA '87 also improved upon the automatic newborn eligibility requirement of DEFRA '84; accelerated coverage of low-income children under five and extended the option of coverage to age eight; and mandated continued coverage of children under the age of seven whose eligibility had been mandated by DEFRA '84. Id; see DEFRA '84, Pub.L. No. 98-369, sec. 2361 (b), 98 Stat. 494, 1104 (codified as amended at 42 U.S.C. 1396d (Supp.1989)).

HCFA has never issued rules to implement the large majority of these provisions. Just two provisions -- coverage of financially needy children ages five to seven and a technical amendment dealing with post-partum eligibility -- were incorporated into the February 1989 Notice of Proposed Rulemaking, which proposed rules to implement the COBRA '85 amendments. 54 Fed. Reg. 7,798 (February 23, 1989). A final rule has still not been issued on these provisions.

The Preamble to the February 1989 proposed rule, published fourteen months after the enactment of OBRA '87, stated that the law's other provisions for poor pregnant women and children were "being incorporated into a separate document." 54 Fed. Reg. 7,798 (February 23, 1989). To date, that document has never been issued, leaving the states without guidance for implementing the expanded coverage options passed by Congress.

4. Third Party Liability

The regulatory history of third party liability further demonstrates HCFA's selective implementation pattern. Prior to 1984, states were permitted (but not mandated) to require Medicaid applicants to assign to the state agency their rights to medical support and third party payments (e.g., from private insurance) for medical care. Approximately 25 states had taken advantage of that provision. 50 Fed. Reg. 46,652 (Nov. 12, 1985). Congress then passed DEFRA '84, which included a mandatory third party liability assignment provision projected to save the federal government $22 million over four fiscal years. Senate Finance Committee Report, Deficit Reduction Act of 1984, April 2, 1984 (CCH Medicaid & Medicaid Guide No. 423, p. 955, April 13, 1984). HCFA incorporated some of these provisions into a final rule strengthening the third party liability provisions.

By 1985, however, it had become clear that certain modifications of the third party liability system were essential in order to assure that the procedures used to assign third party payment rights did not interfere with ready access to maternal and child health services. Congress added these protections to the statute over HCFA's objections. See COBRA '85, Pub.L. No. 99-272, sec. 9503(a), 100 Stat. 82, 205-6 (codified as amended at 42 U.S.C. sec. 1396a(a)(25) (Supp. 1989)) (1986). HCFA issued its second round of third party liability regulations in February 1987. 52 Fed. Reg. 5,967 (February 27, 1987). This final rule incorporated some of COBRA '85's third party liability changes, but still made no mention of the protections for pregnant women and children. These vital safeguards were not added to the third party regulations until January 1990, four years after the changes were enacted. 55 Fed. Reg. 1,423 (January 16, 1990).

5. Medicare Catastrophic Coverage Act of 1988

In 1988, Congress continued its incremental improvements in Medicaid for pregnant women and low-income children by making mandatory the 1986 option to extend coverage to all poor pregnant women and infants. These amendments were contained in the Medicare Catastrophic Act of 1988 (MCCA), Pub.L. 100-360, sec. 302, 102 Stat. 684, 750-4 (codified as amended at 42 U.S.C. sec. 1396a (Supp.1989)). Although the Medicare portions of this legislation subsequently were repealed, the Medicaid provisions remain law.

MCCA required states to extend Medicaid coverage to all pregnant women and infants under age one with family incomes below 100 percent of the federal poverty level (at the time of passage, $9,690 per year for a family of three). MCCA also established certain reimbursement protections for hospitals that provide a disproportionate amount of care to low-income persons by requiring states to lift any "durational" limits otherwise imposed on allowable Medicaid inpatient stays for infants. This amendment was intended to ensure that hospitals furnishing a large volume of care to poor infants would have sufficient resources to meet the exceptionally high costs of caring for these children.

HCFA has completely failed to publish even a Notice of Proposed Rulemaking implementing the changes from 1986, 1987, or 1988. Only immediately prior to passage of another mandate in the Omnibus Budget Reconciliation Act of 1989, which extended eligibility to all pregnant women, infants and children under age 6 with incomes below 133 percent of the federal poverty line, did HCFA issue a Notice of Proposed Rulemaking. 54 Fed. Reg. 39,421; OBRA '89, Pub.L. No. 101-239, sec. 6401, 103 Stat. 2106, 2258-9 (to be codified at 1396a, 1396r-7). The stated goal of this September 26, 1989 Notice was to implement a few of the 1987 and 1988 amendments. No rules implementing the OBRA '86 amendments have yet appeared.

6. Transitional Medicaid Coverage for the Welfare-to-Work Population

HCFA has failed to publish any regulations, proposed or final, on a highly innovative Medicaid benefit that allows families making the transition from welfare to work to retain Medicaid coverage during a 12-month transitional period. Again, this is a case in which the Administration actively opposed the creation of the benefit during the legislative process and sought to water it down and eliminate it throughout consideration of the bill.

The Family Support Act of 1988 established the transitional benefit program because of an extraordinary lack of health insurance coverage among employed former welfare beneficiaries. Pub.L. No. 100-485, sec. 303, 102 Stat. 2343, 2385-93 (codified as amended at 42 U.S.C. 1396r-6 (Supp.1989)). Congress noted that being employed is no guarantee of being insured -- 87 percent of all uninsured Americans are in families in which the head is in the workforce for at least part of the year. The chances of being uninsured are even higher for former welfare recipients. Because these family heads are particularly likely to be young, female, poorly educated, in the service economy and working at extremely low-paying jobs, they are even more likely than poor workers generally to be completely uninsured. The 1987 Report of the House Energy and Commerce Committee accompanying the measure which created the transitional Medicaid program noted that "former AFDC families that work their way off welfare have the greatest need for health care coverage, because they are least able to pay for services out of pocket and because their health is more likely to be poor. Yet these are precisely the families that are among those most likely to be uninsured." (H.R. Rep. No. 159, 100th Cong., 1st Sess., pt. 3, at 12).

Despite the importance of the 1988 transitional Medicaid provisions in reducing the incentive to remain on welfare, and in protecting vulnerable families, HCFA has issued no rules to date, either proposed or final. Informal, unpublished guidance was issued by HCFA in March 1990, 17 months after the law's enactment and only one month before its effective date. State Medicaid Manual, Part 3, Transmittal No. 42 (March 1990). HCFA's delay left states with an impossibly short lead to implement the transitional Medicaid program before the April 1, 1990 effective date.

7. Transitional Child Support

In 1984 Congress established another "transitional" Medicaid eligibility program, this one designed to avoid penalizing families receiving increased child support payments as a result of the Child Support Enforcement Amendments of 1984. Pub.L. No. 98-378, sec. 20, 98 Stat. 1305, 1322 (codified as amended at 42 U.S.C. sec. 606 (Supp.1989)). This transitional child care benefit preserves Medicaid eligibility for women and children when increased collections of cash child support owed the family results in its disqualification for AFDC. HCFA has published no rule to date, proposed or final, to implement these protections.

Another AFDC program change designed to assist AFDC beneficiaries likewise has been ignored by HCFA. Furthermore, although every state will be required to implement an AFDC-UP program effective October 1, 1990, HCFA has not yet even issued a Notice of Proposed Rulemaking.

8. Medicaid Eligibility for Certain Immigrants

From Medicaid's inception in 1965 until 1973, Medicaid benefits were available to all eligible aliens. The original Medicaid statute itself did not contain any citizenship or lawful alienage requirements. In 1973, the Department, without any statutory authority, promulgated regulations to require states to limit aliens' eligibility to those who were permanent residents and aliens permanently residing under color of law ("PRUCOL"). These regulations were challenged and overturned by a federal court. Lewis v. Gross, No. CV-79-1740 (E.D.N.Y., July 14, 1986).

In response, Congress passed a legal residency test in OBRA '86. Pub.L. No. 99-509, sec. 9406, 100 Stat. 1874, 2057-8 (codified as amended at 42 U.S.C. 1396b (Supp. 1989)). The statute restricted Medicaid eligibility to citizens and aliens who are either permanent residents or PRUCOL, with a narrow exception for certain services. OBRA '86 made clear that coverage of emergency treatment, including care for women in active labor, was still required for all "otherwise eligible" aliens, even those in the country illegally.

When Congress legislated the PRUCOL standard, it chose not to define it statutorily. Rather, the House Budget Committee in its report stated, "The Committee intends that the Secretary and the states broadly interpret the phrase 'under color of law' to include all of the categories recognized by immigration law, policy, and practice." H.R. Rep. No. 727, 99th Cong., 2d Sess. 111, reprinted in 1986 U.S. Code Cong.& Admin. News 3607, 3700-01. A clear definition of eligibility for PRUCOL status is important because it establishes eligibility for Medicaid benefits. Instead of issuing a clear definition, however, HCFA waited two years to issue an Notice of Proposed Rulemaking for this complex and undefined statutory amendment which expressly delegated to the Secretary responsibility for legislative interpretation. 53 Fed. Reg. 38,032 (September 29, 1988). No final rules have been issued to date, even though the federal immigration laws are a maze of confusing eligibility criteria that compel careful administrative guidance from the Department.

As a result, states that have large populations of indigent immigrants have been forced to shoulder uncompensated care burdens, when Federal Financial Participation may have been available. Furthermore, innumerable immigrants who qualify for Medicaid have been denied access to coverage because of confusion surrounding eligibility criteria.

Conclusion

Over the last decade, Congress has expanded Medicaid eligibility for approximately a half-million pregnant women and one million children, in a series of incremental program expansions from 1984 through the present. Not only do HCFA's published rules reflect virtually none of these major program changes, but in numerous instances HCFA's rules and policies undermine them. Moreover, HCFA has moved selectively by addressing only those expansions affecting small groups of children, while completely ignoring legislation that has mandated coverage of a much larger number of newly eligible pregnant women and children. The Administration also has consistently ignored every other expansion it opposed --for desperately poor families surviving on meager levels of child support, for disabled foster care and adoptive children, and for families making the transition from welfare to work. At the same time the agency has actively implemented reforms designed to cut eligibility, reduce benefits and make program administration more difficult.

By its very inaction, except through the occasional informal (and unpublished) agency transmittal, HCFA has gravely harmed the Medicaid program. There has not been a working, accurate set of Medicaid eligibility regulations since 1980. Beneficiaries and providers are left in a constant state of confusion about what is or is not covered, and states cannot determine with any accuracy when federal financial aid will be forthcoming. The eight case studies clearly demonstrate that HCFA's Medicaid rulemaking process has undermined the mission of the program to provide health care to the poor, particularly pregnant women and children.

PART TWO: Assessment of the Federal Administrative Conference Draft Recommendations

HCFA's persistent and blatant attempts to undermine Congress' efforts to increase Medicaid's protection for America's most vulnerable citizens -- pregnant women and children -- must be checked. Several of the draft recommendations of the Federal Administrative Conference, such as ending politically motivated delay, and requiring publication of major legislative changes with opportunity for public comment, would further this goal. Other recommendations, such as a Congressional moratorium on Medicaid expansions, would merely reward HCFA for its illegal and detrimental actions at the expense of the health and lives of low-income families.

1. Federal Administrative Conference Draft Recommendations to Congress

A. FAC Recommendation: Moratorium on Major Changes

The FAC is considering a recommendation that "Congress should consider a moratorium on enactment of major changes in the Medicaid program to enable HCFA to catch up with prior changes and to develop the requisite rules and policy to implement past legislative changes completely and properly. During the moratorium, however, Congress should reexamine the program's daunting complexity with regard to eligibility issues in particular, but also issues related to the scope of benefits and the payment of providers." FAC, Draft Recommendation: Rulemaking and Policymaking in the Medicaid Program 6 (May 18, 1990).

We adamantly oppose the suggestion that Congress place a "moratorium" on major program changes. As discussed in our case studies, the majority of the changes taking place in Medicaid during the past decade were designed largely to improve medical services to prevent the needless illness, disability and death that disproportionately falls upon low-income pregnant women and children. Furthermore, this incomprehensible recommendation merely rewards HCFA's bad behavior of the last decade. To recommend a moratorium based on administrative convenience when lives and health of our most vulnerable citizens are at stake profoundly misapprehends the relative importance of fixing this nation's tragic child health problems versus fixing HCFA's damage to the regulatory process.

B. FAC Recommendation: Delay of Effective Date

The FAC has recommended that "Congress should consider delaying the effective dates of legislative changes in the

Medicaid program to the end of the ensuing fiscal year or later, to enable HCFA and states to promulgate the requisite rules or policies for proper implementation of the legislative change." FAC, p.6.

We oppose this recommendation. First, the federal budget process does not permit delaying the expenditure of funds beyond the fiscal year in which that expenditure is authorized. Second, states do not need years to implement most Medicaid changes--the effective date language is by now boilerplate, and virtually every state Medicaid agency has a sophisticated staff capable of understanding Congressional legislation. Neither will delay of the effective date to ensure the development of comprehensive rules result in a decrease in the widespread disallowance problems, since states operate under a number of disallowance actions at any given time even after regulations are in place.

C. FAC Recommendation: State Rulemaking

The FAC also has proposed that where "Congress mandates a program change without regard to whether HCFA promulgates implementing regulations, Congress should specify that states be permitted to engage fully in state rulemaking procedures, especially those designed to assure widespread public participation, before the congressionally-mandated change becomes effective." FAC, pp. 6-7.

The recommendation that a state rulemaking process can supplant HCFA's rulemaking process is specious. HCFA's egregious delay in issuing regulations to which it is politically opposed is the reason why Congress now provides for legislative program changes to become effective without regard to whether HCFA promulgates implementing regulations. In addition, this statutory language is unnecessary, since legislation is always effective regardless of the issuance of regulations. A state level rulemaking process cannot fulfill the public notice and comment requirements needed for implementation of a federal law. Finally, states already are allowed to sustain their own rulemaking process. Congressional legislation is not needed to permit states to follow their own process.

D. FAC Recommendation: Waiver of Administrative Procedure Act

The FAC has suggested that, where "Congress mandates implementation of a statutory change in the Medicaid program, either immediately or within a short period of time, Congress should consider expressly waiving the promulgation and publication requirements of the APA regarding legislative rules. As it has for the Medicare program, Congress should also consider authorizing promulgation of interim final rules with a comment period for regulations that must be implemented in a short time frame. At least, Congress should consider waiving the penalties on states, providers and beneficiaries for failure to comply with the rules until HCFA has complied with the promulgation and publication requirements of the APA or other statutory authority." FAC, p. 7.

The first part of this recommendation is quite puzzling, since HHS already has the authority to waive its own compliance with the APA. However, although the agency has attempted in the past to waive its voluntary compliance with the APA, it has not done so because of the massive public outcry which arose when HHS proposed doing so earlier in the decade. As for waiving penalties, we do strongly support the waiver of penalties until the agency has completely followed the regulatory process.

2. Federal Administrative Conference Draft Recommendations to Health Care Financing Administration

A. FAC Recommendation: Prompt Rule Issuance

The FAC has recommended that, when "Congress mandates a program change, particularly with respect to expanded benefits or tighter regulation of providers, HCFA should act promptly to issue rules and policies to implement the change even if HCFA, HHS, or the executive branch opposed the legislative change." FAC, p. 5.

We agree that HCFA should not hold hostage, policies and guidance implementing legislation to which it is opposed, as it has done in the past. It is important to note, however, that while we believe a comprehensive set of Medicaid rules is desirable, because it makes the program easier for the states to administer, regulations or guidance usually are not legally necessary to create the beneficiary's entitlement to health care coverage, nor the provider's right to payment. Unlike other regulatory programs, the federal agency administering Medicaid does not need to set substantive standards, because Medicaid is an entitlement, and because in almost all instances Congress has not given HCFA legislative rule-making authority. In those few areas where legislative rule-making is required, HCFA has demonstrated consistently a pattern of obstructionism and foot-dragging. HCFA's unwillingness to execute those few statutory obligations called for by Congress highlights the need for the proposed directive for prompt issuance of rules and policies.

B. FAC Recommendation: Publication with Opportunity for Comment

The FAC has recommended that HCFA "should publish all major interpretative and procedural rules as well as general statements of policy in the Federal Register, preferably before adoption or, if not feasible, following adoption. HCFA should invite comments from affected parties regardless of when the rule is published."

We support totally the recommendation for publication, because publication for comment plays an important role in notifying the public of changes in the program, and because it reduces variation among regions. However, we believe HCFA should comply with the prior public comment procedure established by the Administrative Procedure Act.

Sparing use of "interim final" regulations, where the public is invited to comment after issuance, may be appropriate in narrow circumstances, such as when a statutory change takes immediate effect and interpretation is necessary, or when Congress sets a tight deadline for publication of regulations. However, experience shows that HCFA uses the "publish first, comment later" process in a plethora of situations where there is no excuse for barring public participation. Furthermore, as our case studies illustrate, the "comment later" method establishes no incentive for HCFA ever to acknowledge or act upon the public comments, a fact upon which HCFA has capitalized.

In addition to the need for HCFA to publish proposed rules in the Federal Register, with notice and opportunity to comment, it is absolutely essential that HCFA publicly publish its interpretive rules, such as the transmittals issued as amendments to the State Medicaid Manual. The State Medicaid Manual, and other non-public written interpretations, form the true backbone of Medicaid's policies. An annual subscription to the Manual costs approximately $1,000, a price which clearly limits access to HCFA's interpretations. HCFA either should periodically public the State Medicaid Manual in full in the Federal Register, or issue the transmittals as proposed rules, so that the public, including providers, beneficiaries, and other state and federal agencies that interact with Medicaid, have access to the basic written rules and policies of the program.

C. FAC Recommendation: Approval of State Plan Amendments

The FAC has recommended that, where Congress "mandates that states implement a program change by a specific deadline without regard to whether HCFA promulgates implementing regulations, HCFA should not delay approval of state plan amendments but let them become effective 90 days after submission unless otherwise approved or definitively disapproved." FAC, p. 5.

We agree that states should not be unfairly penalized for implementing the law without adequate HCFA guidance, particularly when HCFA later looks to impose highly dubious retroactive rules restricting eligibility or benefits. We are, however, concerned that any reforms to the penalty system take account the inherent unfairness of the Medicaid penalty system. Because the only type of penalty is the withholding of Federal Financial Participation (FFP), HCFA has authority only to penalize those states that are overly generous in its administration (those states that "wrongfully" spent federal funds). HCFA has no proactive authority to penalize state programs that are overly restrictive in nature. Therefore, the proposed "automatic approval" of state plan amendments would not address the serious problem of states' failure to fully and legally implement Congressionally mandated changes in Medicaid.

D. FAC Recommendation: Limited Penalty Moratorium

The FAC has proposed that HCFA "should consider a moratorium of a limited time on the imposition of penalties on the basis of mistakes resulting from states incorrectly implementing a new federally mandated program change." FAC, p. 6.

We believe that a limited moratorium is wise, given HCFA's practice of failing to issue states any guidance at all prior to the effective date of changes, or issuing the guidance so late that states lack adequate lead time. As discussed above, we recommend a waiver or suspension of penalties until HCFA has implemented correctly the regulatory process.

E. FAC Recommendation: Negotiated Rulemaking

The FAC has recommended that, for "program changes that are controversial but nevertheless might be amendable to negotiation, HCFA should consider negotiated rulemaking based on recommendations of the Conference. Negotiated rulemaking could be especially useful on issues of primary interest to states in the management of their programs." FAC, p. 6.

Although we generally support the process of negotiated rulemaking, this model would be ineffective for "controversial" changes in Medicaid. First, the very definition of "controversial" is subjective, and in the Medicaid rulemaking process simply means that HCFA dislikes Congressional legislation. Second, HCFA, unlike other agencies that act as arbiters in a negotiated rulemaking setting, is certainly not a neutral party. Third, Medicaid beneficiaries generally are politically powerless, and the assumption that their interest would be adequately represented in the bargaining process is naive and dangerous.

We are pleased that the Federal Administrative Conference is investigating ways to improve the Medicaid rulemaking process, and appreciate the opportunity to comment.

Very truly yours,

Sara Rosenbaum
Sara Rosenbaum
Director of Programs and Policy

Molly McNulty
Molly McNulty
Senior Health Specialist

Medicaid Rulemaking at U.S. Health Care Financing Administration

September 6, 1990

TYPE OF CONGRESSIONAL ACTION	TIME ELAPSED BETWEEN CONGRESSIONAL ACTION & HCFA ACTION	TIME PERIOD BETWEEN NPRM & FINAL RULE
1. ELIGIBILITY REDUCTION	TWO MONTHS	NONE ISSUED (NINE YEARS)
OBRA 1981 Pub.L. 97-35		
2. CONGRESSIONAL LEGISLATION TO OVERTURN UNLAWFUL HCFA RULINGS	NONE ISSUED	NONE ISSUED
TEFRA 1982 Pub.L. 97-35	8 YEARS TO DATE	NONE ISSUED
DEFRA 1984 Pub.L. 98-369	6 YEARS	NONE ISSUED
PPA 1987 Pub.L. 100-93	3 YEARS	NONE ISSUED
3. ELIGIBILITY EXPANSION		
DEFRA 1984 Pub.L. 98-369	1 YEAR	3 YEARS
COBRA 1985 Pub.L. 99-272	NONE ISSUED	2 YEARS AT 1ST, 5 YEARS FOR REST
4. ELIGIBILITY EXPANSION & PROTECTIONS		
COBRA 1985 Pub.L. 99-272	4 YEARS	3 YEARS
OBRA 1986 Pub.L. 99-509	NONE ISSUED	NONE ISSUED

Mr. WAXMAN. Thank you very much, Ms. Johnson.

Mr. Gehring.

STATEMENT OF RICHARD GEHRING

Mr. GEHRING. Thank you, Mr. Chairman.

My name is Richard Gehring. I am chairman of the board of directors of the Alzheimer's Association. I am also a family care giver. I am delighted to appear before you today in support of H.R. 3933, the Medicaid Frail Elderly Community Care Amendments.

This legislation is a top priority for the Alzheimer's Association. We are grateful to you, Mr. Chairman, and to Mr. Wyden for your leadership and persistence in moving this bill forward. If you understand the havoc Alzheimer's wreaks on the patient and the patient's family, you understand why this bill is so important.

Alzheimer's is the ultimate long-term care problem in this country because of the duration of the disease and the intensity of the care it requires.

It is a disease for which there is no prevention, no cure, no treatment, only compassionate care. My wife has been suffering from Alzheimer's disease for 17 years. At 64, she is physically strong and could live for a number of years. Before the disease struck, she was the kindest, most intelligent person you could imagine. Today she cannot feed or dress herself. She cannot walk or talk. She no longer knows who I am. She needs total care 24 hours a day.

Like most families, I cared for my wife at home as long as I could, for 9 years. At first, she didn't need skilled nursing care, a companion provided security and assistance. As her behavior became more difficult and her abilities more impaired, it was harder to find and keep help.

When my job required moving to New York City and frequent travel, I took early retirement. We moved in with her parents. They were in their eighties and frail themselves. By now my wife was occasionally physically abusive and I could not leave them alone together.

I became her full-time caregiver. Finally, when I could no longer manage, we made the painful decision to place her in a nursing home where she has lived for nearly 8 years. I was lucky. I could pay for my wife's care. I could afford to retire early so I could keep her at home as long as possible.

Hundreds of thousands of American families are not so fortunate. When you get a diagnosis of Alzheimer's disease, the doctors tell you there is nothing we can do. The government says there is nothing we will do. You are on your own. You and your family, until you are totally exhausted, emotionally, physically, and financially. What a perverse public policy.

We are one of the only industrialized western nations that doesn't have a long-term care system for their elderly. Wouldn't it be better if this country said to the family, we are in this together. We will give you some help before you are broken financially and physically.

H.R. 3933 is a modest affordable first step toward a rational long-term care policy. It starts where it must, with the very poorest and frailest elderly persons. This bill takes its lead from the States that have been the last for long-term care.

At least 38 States now have waivers to use some of their Medicaid funds to provide services in the community. That should tell us something. My written statement includes a number of specific recommendations and comments about the bill. I want to mention just one.

That has to do with family caregivers. In many cases family members can provide the best care. In some cases they are the only ones who can provide the care. This bill is designed for those who are living at the very margin, where minimal earnings of a spouse or an adult child may be all the family has to pay the bills.

If that breadwinner has to quit or reduce hours of paid employment to care for a frail elderly person, then the most practical and the most humane thing to do may be to pay that family member to provide care. Mr. Chairman, our country's current budget problems are not an excuse for inaction.

H.R. 3933 does not require new spending. It simply gives States an option under Medicaid. If a State decides that home and community care should be a priority, even in tight budget times, then the Federal Government should not stand in its way.

You are hearing this morning about four of the worst tragedies that strike American families. Don't force yourself to choose between them. It would be a sorry comment about our Nation if we cannot find a way to provide this modest beacon of hope and help to all of the families you have heard about today.

I thank you and I would be happy to respond to any questions.

[The prepared statement of Mr. Gehring follows:]

PREPARED STATEMENT OF RICHARD GEHRING, ON BEHALF OF THE ALZHEIMER'S ASSOCIATION

Mr. Chairman and Members of the Subcommittee. My name is Richard Gehring. I am Chairman of the Board of Directors of the Alzheimer's Association. I am also a family caregiver. My wife has Alzheimer's disease.

The Association is the national voluntary health agency dedicated to finding a cure for Alzheimer's disease and to easing the burden of the 4 million Americans who suffer from it, their families, and their loved ones. We work through 210 chapters and over 1600 support groups in every part of the country.

I am delighted to appear before you today in support of H.R.3933, the Medicaid Frail Elderly Community Care Amendments of 1990. Enactment of this legislation has been a top priority for the Association for the past two years. We are grateful to you, Mr. Chairman, and especially to Mr. Wyden for your leadership and your persistence in moving this bill forward, even in this difficult budget year.

This Subcommittee, I know, understands what a devastating disease Alzheimer's is. It robs the patient of memory, judgment, reasoning—everything that makes a person a unique human being. And it wreaks havoc on the family, as they struggle to care for a loved one who is gradually disappearing before their eyes.

Alzheimer's is the quintessential long term care problem—because of the duration of the disease and the intensity of care it demands.

My wife has been suffering with Alzheimer's for 17 years. She is still physically strong and could live for a number of years to come. But she can do absolutely nothing for herself.

Before the disease struck, she was the kindest, most graceful person you can imagine. Today, she cannot feed or dress herself. The beautiful woman I married no longer knows who I am. She cannot walk or talk. She cannot follow instructions or respond to communication. She needs total care—24 hours a day.

Like most family members, I cared for my wife at home as long as it was possible to do so—for nine years. When she was first diagnosed, we were living in suburban Philadelphia and I was commuting to New York. I couldn't leave her alone at home, and I couldn't take her with me every day. She did not need skilled nursing care. But she did need a constant companion, whom I hired at a cost of $300 to $400 a week.

That worked well for quite some time. But as her behavior became increasingly difficult to manage, it became harder and harder to find and keep help. Things finally came to a head when my job required that I move to New York City. I did not see how I could handle that—with no friends and no support system. I took early retirement and we moved back to Minnesota, where most of our family lived.

We moved in with her parents, but that did not work out as well as I had hoped. They were in their 80's and very frail. My wife would physically assault her mother. I could not leave them alone together. I was the only one who could deal with her, and I became her full-time caregiver. Finally, when I could no longer manage, we made the painful decision to place her in a nursing home, where she has lived for the past 8 years.

I was lucky. I had a high-paying job and a responsible position in business. I had the money to pay for her care and friends and family who did all that they could to help. When the time came, I could afford to retire early. Hundreds of thousands of American families are not so fortunate.

When you get a diagnosis of Alzheimer's disease, the doctors tell you, "There is nothing we can do."

The government says, "There is nothing we will do. You're on your own until you are totally exhausted—emotionally, physically, financially."

What a perverse public policy! How much better it would be if we had a long term care system in this country that said to the family, "We're in this together, for the long haul. We'll help you get through this with dignity and at least some sense of security."

H.R.3933 is a modest and affordable first step toward a rational long term care policy in this country. It starts where we must, with the very poorest and frailest persons living in the community.

Starting small, it will help states build the infrastructure that must be in place for a more comprehensive long term care system to work. The bill does several things that are essential to long term care: It moves away from the institutional bias and the traditional medical model of care that has marked our approach to this problem over the years; it firmly establishes essential principles for the definition of functional disability that are appropriate to long term care; and it insists on components critical to quality and cost control—case management, care planning, and quality assurance.

H.R.3933 was not created in a vacuum. Rather, it takes the lead from the states, which have been the laboratory for long term care in this country.

At least 38 states have obtained waivers from the federal government to use some of their Medicaid funds to provide services in the community. That should tell us something. When the exception becomes the rule, it is time to reexamine the rule.

It is important to understand that this bill does not establish any new federal mandates. Rather, it takes the best practices that exist out there in the states and gives all states the option to begin to implement them.

The bill removes the administrative "hoops"—the months and sometimes years of paperwork that some states have faced, trying to get approval from the federal government to implement the program they have developed.

We do want to make one important point. In an effort to extend the option to all states within current budget constraints, H.R.3933 provides for a very modest program. Some states are now operating waiver programs that go beyond the authority in this bill. Congress must make clear to the states and to HCFA that enactment of H.R.3933 does not preclude states from continuing broader waiver programs and, in fact, we encourage them to do so.

We have several recommendations for changes in H.R.3933 which we believe would strengthen the bill, while keeping it within the modest parameters you have set for legislation.

(1) *Eligibility definition.* H.R.3933 recognizes that traditional tests of activities of daily living are not adequate measures of functional disability or the need for long term care—particularly for persons suffering from cognitive impairments like Alzheimer's disease. By adding measures of need for supervision, physical cueing and verbal reminding, as well as need based on problem behavior, this bill takes a major step forward in the development of long term care policy in this country.

We share the concern expressed by others about a disease-specific eligibility test. At the very least, we would like to see a broader definition that includes the "related disorders"—dementias that are caused by diseases other than Alzheimer's. Because Alzheimer's disease is by far the most common cause of dementia in the elderly, we do not believe this broader language would add significantly to the cost of the bill. But it would remove any temptation to overdiagnose Alzheimer's to assure a person's access to service.

We also urge you to move as quickly as possible to include all financially eligible persons who are functionally disabled because of cognitive or other mental impairments, without regard to the underlying cause of that impairment.

As long as funds are limited, however, Alzheimer's is a good place to start, because it is the quintessential long term care problem. If we can develop a long term care system that will work for Alzheimer patients and families, we will have a system that should work for everyone.

(2) *Income Eligibility.* The financial eligibility limits in H.R.3933 create an anomaly. The intent of the bill is to help families keep their loved ones at home. But a family will be able to qualify for nursing home care before it can qualify for care in the community. We urge you to amend the bill to allow states to set the same income eligibility levels for those receiving care at home as they have set for those receiving care in nursing homes, and to apply the spousal impoverishment protections that now apply for nursing home care to the services provided under this bill.

(3) *Family Caregivers.* The prohibition on payment of family caregivers puts unwise and unnecessary constraints on the states. At least 70 percent of the states now operating 2176 waiver programs pay family caregivers in some circumstances. There is no evidence of abuse.

In many cases, family members are the best caregivers. In some cases, like my own, they are the only one who can provide care. I could afford to do it, but this bill is not for people like me. It is designed to help those who are living at the very margin, where minimal earnings of a spouse or an adult child may be all that is available to meet the family's basic living needs. In those cases, the most practical, not to mention the most humane thing to do may be to pay that family member to provide care.

Appropriate limits could be placed on such payments—for example, providing them only for a family member who must quit or cut back paid employment to become a caregiver. We urge that you take the position of the Senate bill, that is to preserve the option for states to pay family caregivers in circumstances they consider to be appropriate and in the best interests of the patient.

(4) *Maintenance of State Effort.* It is important to assure that the end result of enactment of H.R.3933 is the expansion of home and community services to the frail elderly. We share the sponsors' concern that federal Medicaid funds not be used to replace current state expenditures. On the other hand, Congress should not penalize states that have taken the initiative and provided leadership in developing long term care services for their citizens. The bill should allow states to use funds they are now spending for long term care services to this population to match Medicaid funds and expand these services.

When the House of Representatives passed its budget resolution last spring, you recognized that the cost of this bill was modest enough, and the services so essential, that the resolution should make room for its enactment this year. Nothing has happened that should change your minds now.

This bill does not require new spending. It simply gives states an option under the Medicaid program. States are coping with the same kinds of budget problems as the federal government. If a state decides that home and community care should be a spending priority, even in tight budget times, then the federal government should not stand in its way.

We understand that the White House and Congress are seeking a five-year budget agreement. If that is so, then it is even more essential to enact this modest proposal now, to stake a claim for a reasonable amount of federal expenditures over the next five years to begin to address the long term care problem in this country.

Last year, when the conferees dropped the Medicaid amendments from budget reconciliation, it was with the understanding that you would come back to them this year. Failure to act now may mean putting off any chance of progress, not just for one more year but for at least five years. That is too long to wait.

In conclusion, I would like to comment on the wider range of issues you are addressing today. This panel is testifying about four of the most devastating tragedies that strike American families. We have heard the question, "If you can only do one of these bills, which should it be?"

Don't force yourselves or your colleagues to choose between the young adult with AIDS, the disabled child, the poor mother, or the frail grandparent.

It would be a sorry comment about our kind and gentle nation if we cannot find the way to provide this modest beacon of hope and help to all of the families you have heard about today.

Thank you for giving me this opportunity to testify before you. I will be happy to answer any questions.

Mr. WAXMAN. Thank you very much, Mr. Gehring, for an excellent statement. Mr. Jones.

STATEMENT OF WILLIAM E. JONES

Mr. JONES. To you, Chairman Waxman and members of the subcommittee, the consortium for citizens with disabilities thank you for the opportunity to testify here today.

I am Bill Jones, the executive director of the American Association of University of Affiliated Programs for Persons with Development Disabilities, an organization concerned with training, research, and exemplary services for persons with developmental disabilities.

University Affiliated Programs are authorized under the Developmental Disabilities Assistance and Bill of Rights Act, legislation also under the jurisdiction of this subcommittee.

Today, I am representing the Medicaid long-term task force of the Consortium for Citizens With Disabilities. First, let me address the need to expand Medicaid benefits. We are here to support the package of Medicaid initiatives which will involve modest expansions of Medicaid expenditures in fiscal year 1991.

As organizations representing the interests of persons with disabilities and their families, we support the purposes and concepts of the entire package of Medicaid initiatives. These proposals, which encompass health care and community-based service provision to low income women, infants and children, the frail elderly, persons with HIV infection and terminally ill patients are of critical importance to those segments of a society for whom access to appropriate care is at a minimum difficult and often impossible under current law.

Second, I address the Medicaid Community and Facility Habilitation Services Amendments. As the members of this subcommittee are aware, the issue of reform in the Medicaid program for persons with developmental disabilities has been before Congress for 7 years. Moreover, there have been at least two groups of advocates with different suggestions for remedying the problem.

In spite of these differences all parties agree on two things. One, there are major unmet service needs among persons with developmental disabilities and their families in every State in the Nation, and, two, significant improvements in Medicaid law are essential to address these needs.

The bill under consideration, H.R. 3934, would make two major changes in the current ICFMR and home and the community-based waiver program. First, the bill seeks to ensure the quality of service provided in the ICFMR. It remains a high priority for us to ensure quality services to persons who are considered highly vulnerable by the nature of their disabilities when they receive congregate care services outside their homes.

Second, the bill would, for the first time, create a Medicaid State plan option rather than a Secretarily-approved waiver that would allow the States to provide Medicaid funded services to persons living in their own homes or other community arrangements.

The unmet needs of persons with developmental disabilities living in the community are reaching crisis proportions, as waiting lists approaching 150,000 children and adults for many types of services. In addition, as a result of the federally guaranteed right to education for all children with disabilities under the Education for all Handicapped Children Act of 1975, a significant number of the approximately 50,000 students with mental retardation and related disabilities each year are leaving the entitlement of educational services in which we have all invested, and are placed in lengthy waiting lists and sit at home and unlearn the skills they acquired in the public schools.

This is a tragic waste of human and fiscal resources. This subcommittee made a good start towards addressing these unmet needs in 1981 with the home and Community-Based Care Waiver Program. However, because of critical limitations inherent in the waiver program, it simply is not capable of assisting the States in meeting the unmet needs.

States need greater flexibility to meet the individualized and unique needs of persons with disabilities and their families in the community.

The creation of a new State plan coverage along the general lines proposed in H.R. 3934 would be a logical next step for Congress to take. It is time now to remove the existing bias in the Medicaid statute which continues to direct over 70 percent of Federal Medicaid funds for this population into institutional care.

While we support passage of legislation that contains the basic elements of H.R. 3934, we also urge the subcommittee to address significant concerns regarding certain areas of the bill, including the need of improvements in the community quality assurance provisions, employee protections, maintenance of effort, preadmission screening and annual resident reviews and institutional quality assurance provisions.

Our organizations have previously provided separate recommendations to the subcommittee regarding these needed changes. In addition, we urge the subcommittee to establish a size limit of no more than 8 percent living within a community residential setting eligible to receive funding for services provided under the community services section.

In closing, the Consortium for Citizens with Disabilities that each of the proposed expansions are important, and we urge the subcommittee to resist choosing among these worthy initiatives.

While we recognize that Congress must deal with these issues within a very difficult budget context, we urge you not to ignore the pressing human needs which these initiatives are designed to address. A responsible solution to our Nation's budget difficulties should be developed.

Thank you very much.

[The prepared statement of Mr. Jones follows:]

PREPARED STATEMENT OF WILLIAM E. JONES, ON BEHALF OF CONSORTIUM FOR CITIZENS WITH DISABILITIES

Chairman Waxman, Members of the Subcommittee, thank you for this opportunity to testify here today.

I am Bill Jones, the Executive Director of the American Association of University Affiliated Programs for Persons with Developmental Disabilities, an organization concerned with training, research, and exemplary services for persons with developmental disabilities. The University Affiliated Programs are authorized under the Developmental Disabilities Assistance and Bill of Rights Act, legislation also under the jurisdiction of this Subcommittee. Today I am representing the Medicaid Long Term Care Task Force of the Consortium for Citizens with Disabilities.

We are here to support the package of Medicaid initiatives which will involve modest expansions of Medicaid expenditures in fiscal year 1991. As organizations representing the interests of persons with disabilities and their families, we support the purposes and concepts of the entire package of Medicaid initiatives.

The proposals to provide access to Medicaid services for poor women, infants, and children are important for two reasons. First, they will provide access to medical care to more pregnant women and children from poor families, including children with disabilities who should receive good care. Second, these prevention-related initiatives will go a long way toward reducing the incidence of disabilities in children by ensuring better access to prenatal care as well as appropriate medical care to children of all ages. Those disabilities which can be prevented or ameliorated through good medical care should be of major concern to this Committee. Congress is well aware of the importance of early intervention in reducing the long-term costs of a disability.

We also support the principles undergirding the initiative to provide community-based services, beyond the scope of the current waiver program, to persons who are frail and elderly. As persons with physical and mental disabilities age, the ability to have their needs met while remaining in the community will be can important factor in reducing the need for nursing home care.

Finally, CCD strongly supports the proposal to authorize optional Medicaid coverage of critical HIV-related health care services for certain people who test HIV positive. In many instances, the services covered under the legislation—including laboratory and x-ray services, clinical services, prescription drugs and case management—will be the difference between life and death for thousands of low-income persons with the HIV virus who live in high incidence areas of the United States where access to proper health care is particularly difficult; infants and children with AIDS are also included in the proposal.

The remainder of my remarks will focus on the initiative to provide community and facility habilitation services to persons with mental retardation or related conditions, including cerebral palsy, epilepsy, and autism.

As the Members of this Subcommittee are aware, the issue of reform of the Medicaid program for persons with developmental disabilities has been before the Congress for seven years. Moreover, there have been at least two groups of advocates with different suggestions for remedying the problem. In spite of these differences, all parties agree on two things. One, there are major unmet service needs among persons with developmental disabilities and their families in every state in the nation; and, two, significant improvements in Medicaid law are essential to address these needs.

The bill under consideration, H.R. 3934, would make two major changes to the current ICF/MR and home and community-based waiver programs. First, the bill seeks to ensure the quality of services provided in ICFs/MR. All of our organizations have worked for years to seek and maintain improvements in the quality of services in ICFs/MR since its creation in 1971. Important strides have been made in the last few years and it is critical that we preserve those advances. It remains a high priority for us to ensure quality services to persons who are considered highly vulnerable by the nature of their disabilities when they receive congregate care services outside their homes.

Second, the bill would, for the first time, create a Medicaid state plan option (rather than a Secretarially approved waiver) which would allow the States to provide Medicaid-funded services to persons living in their own homes or other community arrangements.

The unmet needs of people with developmental disabilities living in the community are reaching crisis proportions, as waiting lists continue to grow. Current estimates by advocacy groups and state agencies indicate that between 100,000 and 150,000 children and adults with developmental disabilities and their families are waiting for some type of service. In addition, as a result of the federally guaranteed right to education for all children with disabilities under the Education for all Handicapped Children Act of 1975, a significant number of approximately 50,000 students with mental retardation and related conditions who each year are leaving the entitlement to educational services in which we have all invested, are placed on lengthy waiting lists and get to sit at home and "unlearn" the skills they acquired in the public schools. This is a tragic waste of human and fiscal resources.

This Subcommittee made a good start toward addressing these unmet needs in 1981 with the Home and Community-Based Care Waiver program. However, because of critical limitations inherent in the waiver program—its time-limited nature, the inability of States to make long-term community services plans, its linkage to the State's ICF/MR program, the requirement for people served to be at risk of institutionalization, and a cap on the number of people served in a State's waiver—the waiver program by itself is not capable of assisting the states in meeting the unmet needs.

States need greater flexibility to meet the individualized and unique needs of persons with disabilities and their families in the community. The creation of a new state plan coverage along the general lines proposed in H.R. 3934 would be a logical next step for Congress to take. It is time now to remove the existing bias in the Medicaid statute that continues to direct over 70 percent of federal Medicaid funds for this population into institutional care. By eliminating this institutional bias from Medicaid law, Congress would be taking an important step towards allowing individuals and their families to gain access to a range of options that best address their needs.

While we support passage of legislation that contains the basic elements of H.R. 3934, we also urge the Subcommittee to address significant concerns regarding certain areas of the bill, including the need for improvements in the community quality assurance provisions, employee protections, maintenance of effort, preadmission screening and annual resident reviews, and institutional quality assurance provisions. Our organizations have previously provided separate recommendations to the Subcommittee regarding these needed changes. In addition, we urge the Subcommittee to establish a size limit of no more than eight persons living within a community residential setting eligible to receive funding for services provided under the community services section.

The Medicaid expansion initiatives which the Subcommittee has under consideration will by no means solve all the problems associated with meeting the acute and long term care needs of economically deprived populations within American society. However, they do represent long overdue steps in the right direction. Each of the proposed expansions are important and we urge the Subcommittee to resist any temptation to choose among these worthy initiatives.

While we recognize that Congress must deal with these issues within a very difficult budget context, we urge you not to ignore the pressing human needs which these initiatives are designed to address. A responsible solution to our nation's budget difficulties should be developed which does not ignore the pressing needs which these carefully targeted expansions in Medicaid benefits represent. Failing to address the pressing human needs will only serve to exacerbate them.

Thank you for your time. I would be happy to answer any questions you may have.

Mr. WAXMAN. Thank you much, Mr. Jones.

Ms. McGuire.

STATEMENT OF JEAN F. McGUIRE

Mr. MCGUIRE. Yes, Congressman. I am Jean McGuire, executive director of the AIDS Action Council. The council represents over 500 AIDS service organizations around the country that are at the front lines of this epidemic. I also chair the National Organizations responding to AIDS which has endorsed the legislation we are discussing today.

I am very pleased to be here with my colleagues in support of the Medicaid improvements in front of us.

We each represent groups of individuals who are seriously disenfranchised from access to appropriate and necessary health care. All of the proposals under consideration today address troubling gaps in our Nation's health care system for the poor and ill.

In the context of HIV, those gaps are becoming more apparent and more alarming as we encounter the changing demographics of the expanding case load, more people of color, more women, more children, more poor.

As an indicator of this trend, gay, bisexual men who initially accounted overwhelmingly for the majority of reported AIDS cases comprised only 56 percent of the cases reported to the CDC in the last year. Giving further evidence to the increasing poverty based experience of this disease is the expanding role that Medicaid and other public sources are playing in the paying for AIDS-related care throughout the country.

The best source of data illustrating this trend has been the studies conducted by the National Public Health Association, which most recently showed that as an average Medicaid paid for 44 percent of the hospital admissions associated with AIDS diagnosis and that public funds collectively paid for 52 percent in certain jurisdictions.

The change in risk group distributions, the hospital survey information and HCFA's own estimation that it now pays for 40 percent of all AIDS patients at some point in their illness indicate that access and reimbursement concerns for HIV disease among people who are poor, demands thoughtful and aggressive proposals now.

This is just what H.R. 4080 is. You and your colleagues have proposed changes to the Medicaid program which are particularly responsive to the changing needs being faced by consumers and providers in the context of this disease and are fully supported by the AIDS Action Council and the member agencies of NORA.

Since this subcommittee has previously considered the hospital COBRA and pediatric issues at length and since Mayor Dinkins did such a nice job in further describing them earlier, I am going to concentrate the rest of my remarks on the provision, which will allow States to provide certain early intervention services.

During the course of the last year in a series of pronouncements, the Public Health Service indicated that people living with HIV disease who are not yet sick, but have a compromised immune status should be receiving prophylactic treatment with AZT.

In addition, aerosolized pentamiaine was approved for us in primary, as well as secondary prevention of pneumocystis carinii pneumonia. Secretary Sullivan's new standards of care should provide new hope to about 500,000 people who are living with HIV according to CDC estimates. This is possible because of research conducted under the auspices of the same Department of Health and Human Services clearly indicated the progress of this disease can be forestalled, but these pronouncements have been and continue to be but an empty promise of hope for many of the poor who are living with this disease.

Unfortunately, it is not enough, as you well know, simply to be very poor in this country in order to qualify for access to the Nation's poverty health care system. That is Medicaid. One must also be categorically eligible; that is, one must be elderly, pregnant, a child or severely disabled.

Most of the poor with HIV do not fall into any of these categories. Therefore, they must wait until they become sufficiently sick to quality as disabled. In many jurisdictions that means they must have a fullblown AIDS diagnosis. In fact, the Social Security Administration's own data recently indicated that 54 percent of all pre-AIDS HIV related claims for eligibility were denied last year.

At the point at which an AIDS diagnosis has been made, it is too late to offer the hope of prophylactic treatment that Secretary Sullivan has recommended. Without a restructuring of Medicaid the promise of an extended life with HIV will be meaningless to those who are poor.

The experience of HIV is not illuminating a new problem in the Medicaid system. Historically, it has been a system whose biases promote treating illnesses once they become acute, frequently in the most expensive and restrictive settings, as opposed to responding at earlier and often less expensive, stages of intervention, but in the context of HIV, the incongruity of such a system becomes that much more evident and more alarming because the implications are that the opportunity for effective intervention will almost assuredly be passed by the time the individual who is poor becomes eligible for participation in the program.

By effectively denying people access to early intervention, we are also denying them the opportunity to remain healthier, more productive and more independent for longer periods of time.

In addition, we are assuring that the juncture at which they do, in fact, become known to the system will be a high cost one, one from which we can only anticipate further deterioration. Last month the President signed into law another great work by this subcommittee, the Ryan White Comprehensive AIDS Resources Emergency Act. That law will assure that there will be resources for the structures that need to be in place to support the wide range of subacute care services required for an effective national response to the epidemic.

Also because of the foresight of this subcommittee, effective linkages will be established between testing, counseling and treatment efforts, but a discretionary program such as that, even as large as it is, cannot begin to meet the early intervention therapeutic needs of the poor.

Its enactment and funding service serves only as a bridge to more effective reimbursement mechanisms. Those needs and reimbursement mechanisms are rightfully addressed through the proposed Medicaid eligibility expansion in H.R. 4080. In conclusion, with this bill also enacted, the subcommittee will not only have responded humanely to the early intervention needs of the poor, but it will also have successfully addressed the range of pressing rational HIV care needs in a comprehensive, compassionate and effective manner.

We urge adoption and funding of the proposals you put forward. Thank you.

[The prepared statement of Mr. McGuire follows:]

PREPARED STATEMENT OF JEAN F. McGUIRE, EXECUTIVE DIRECTOR, AIDS ACTION COUNCIL

Good morning. I am Jean McGuire, Executive Director of the AIDS Action Council. The Council represents over 500 AIDS service and advocacy organizations at the front lines of the epidemic throughout the country. I also chair the National Organizations Responding to AIDS [NORA] which has endorsed the legislation we are discussing today.

I am very pleased to be here with my colleagues in support of the Medicaid improvements before us. We each represent groups of individuals who are seriously disenfranchised from access to appropriate and necessary health care. All of the proposals under consideration today address troubling gaps in our nation's health care system for the poor and the ill.

In the context of HIV, those gaps are becoming more apparent and more alarming as we encounter the changing demographics of the expanding caseload: more people of color, more women, more children, more poor. As an indicator of this trend, gay and bisexual men, who initially accounted overwhelmingly for the majority of the reported AIDS cases, comprised only 56 percent of the cases reported to the Centers for Disease Control between mid 1989 and mid 1990.

Giving further evidence to the increasingly poverty-based experience of this disease is the expanding role that Medicaid and other public sources are playing in paying for AIDS related care throughout the country. The best source of data illustrating this trend has been the studies conducted by the National Public Hospital Association which, most recently, show that as an average Medicaid paid for 44 percent of the hospital admissions associated with AIDS diagnoses, and that public funds collectively paid for 52 percent. In certain areas of the country, public resources paid for as much as 71 percent.

There are shortcomings in all the indicators we currently have available to estimate the extent to which poor people represent the largest growing population affected by HIV. However, the change in risk group distributions, the hospital survey information, and HCFA's own estimation that it now pays for 40 percent of all AIDS patients at some point in their illness indicate that access and reimbursement concerns for HIV disease among people who are poor demand thoughtful and aggressive proposals—now.

That is just what H.R. 4080 is. Congressman Waxman and his colleagues have proposed changes to the Medicaid program which both improve access to necessary care and enhance reimbursements for those hospitals which are disproportionately carrying the burden of this disease. In addition, the proposals include a cost savings mechanism which would allow states to use Medicaid funds to pay for the extension of private insurance coverage for individuals with HIV disease. The four provisions are particularly responsive to the changing needs being faced by consumers and providers in the context of this disease and are fully supported by the AIDS Action Council and the member agencies of the National Organizations Responding to AIDS.

Since this Subcommittee has previously considered the hospital and pediatric issues at length and the payment of private insurance premiums is actually revenue producing, I am going to concentrate the rest of my remarks on the provision which will allow states to provide certain early intervention services. During the course of the last year in a series of pronouncements, the Public Health Service indicated that people with HIV disease, who are not yet sick but who have a compromised immune status, should be receiving prophylactic treatment with AZT. In addition, aerosolized pentamidine was approved for use in primary, as well as secondary, prevention of pneumocystis carinii pneumonia.

Secretary Sullivan announced new standards of care for over 500,000 people living with HIV (CDC's estimate of the number of people with HIV who have T-cell counts below 500) because the research which had been conducted under the auspices of this same Department of Health and Human Services clearly indicated that progress of the disease could be forestalled. But these pronouncements have been, and continue to be, but an empty promise of hope for many of the poor who are living with HIV.

Unfortunately, it is not enough simply to be very poor in this country to qualify for access to the nation's poverty health care system—Medicaid. One must also be categorically eligible—that is, one must be elderly, a pregnant woman, a child, or severely disabled. Most of the poor with HIV do not fall into any of these categories. Therefore, they must wait until they become sufficiently sick to qualify as disabled. In many jurisdictions, that means they must have an AIDS diagnosis. In fact, the Social Security Administration's own data indicates that 53.9 percent of all pre-AIDS HIV related claims for eligibility were denied in 1989. At the point at which an AIDS diagnosis has been made, it is too late to offer the hope of the prophylactic treatment the Secretary of Health has recommended. Without a restructuring of Medicaid, the promise of an extended life with HIV will be meaningless to those who are poor.

The experience of HIV is not illuminating a new problem in the Medicaid system. Historically it has been a system whose biases promote treating illnesses once they become acute, frequently in the most expensive and restrictive settings, as opposed to responding at earlier, and often less expensive, stages of intervention. But in the context of HIV, the incongruity of such a system becomes that much more evident and more alarming, because the implications are that the opportunity for effective intervention will almost assuredly be passed by the time the individual who is poor becomes eligible for participation in the system.

By effectively denying people access to early intervention, we are also denying them the opportunity to remain healthier, more productive, and more independent for longer periods of time. In addition, we are assuring that the juncture at which they do in fact become known to the system will be a high cost juncture from which we can only anticipate further deterioration.

An unavoidable question is why do this for this disease? Why make a change in the poverty health care system for a certain segment of the poor? None of the answers are wholly satisfactory, but that does not change the compelling need. If the system were not so convoluted in its structure, such a change would not be required. Preventive health care would be a reimbursable element of the continuum of care. Unfortunately, we must conclude that the only way to get the early care prescribed by the Public Health Service to poor people living with HIV is to bypass the problem of total disability.

At a very individual level, we consider this a humane, moral and responsible thing to do. However, at a systemic level we also believe there is a valid rational for pursuing this course. People with AIDS and AIDS related conditions are disproportionately filling our hospital wards, emergency rooms, and public health clinics. By their presence and intense utilization of services they are having an impact on access to health care for poor people who have other medical needs. Preventing deterioration of the health status of people living with HIV and not yet sick will relieve some of the impending disaster in these various public health settings—at least for a time, and perhaps until there are even more effective interventions.

Getting treatment to people early in their disease also provides the opportunity to intervene with them for purposes of behavior change so that they can receive the information and support they may need to assure that they do not continue to spread the disease to others. The treatment relationship thus provides an excellent opportunity to meet both secondary and primary prevention needs.

Last month, the President signed into law another great work of this Subcommittee—the Ryan White Comprehensive AIDS Resources Emergency Act. That law will assure that there will be resources for the structures that need to be in place to support the wide range of subacute care services required for an effective national response to the epidemic. Also, because of the foresight of this Subcommittee, effective linkages will be established between testing, counseling and treatment efforts. But, a discretionary program such as that, even as large as it is, cannot begin to meet the early intervention therapeutic support needs of the poor. Its enactment and funding serves only as a bridge to more effective reimbursement mechanisms. Those needs and reimbursement mechanisms are rightfully addressed through the proposed Medicaid eligibility expansion in H.R. 4080.

With this bill also enacted, the Subcommittee will have not only responded humanely to the early intervention needs of the poor, it will also have successfully addressed the range of pressing national HIV care needs in a comprehensive, compassionate and effective manner. We urge adoption of this legislation and immediate implementation.

Thank you again for your leadership in the fight against HIV.

Mr. WAXMAN. Ms. Johnson, I was struck by the point you made in your statement that average monthly cost of Medicaid for a child is about $80, less than it costs to purchase a monthly parking space at most Capitol Hill area garages. This is, of course, far less than the monthly cost of Medicaid coverage for the elderly or the disabling, which is $363 per month.

This $80 per month figure includes the high cost of caring for low income birth weight babies, doesn't it?

Ms. JOHNSON. It does, in fact.

Mr. WAXMAN. Couldn't we reduce the average cost of Medicaid coverage for poor children if we expanded Medicaid coverage of pregnant women, giving more of them access to prenatal care that could reduce the number of low-birth-weight infants?

Ms. Johnson. Well, we certainly could, Mr. Chairman. We have heard some of the expert evidence presented here today regarding the magnitude of the savings that we might generate through Medicaid investment. We have heard about the Institute of Medicine number that we could save $3 for every $1 we invest in prenatal care, and I would add that that was an estimate for low income women, particularly.

That is where the savings are really to be found, according to the IOM. In addition, the Office of Technology Assessment estimate that we could save between $14,000 and $30,000 for every low birth weight that we could prevent. Finally, the White House Infant Mortality Report found that for each infant death we could be saving $380,000, that is the amount that we are losing in lost productivity, so every year tens of thousands of the 270,000 low-birth-weight births could be prevent, and the savings would be enormous, I think not only in fiscal terms for the Nation, but obviously incalculable in terms of human suffering for the families.

We have just released a report, Mr. Chairman, about progress in maternal and infant health, and in particular looking at prenatal care and low birth weight. What we found was from 1970 to 1979 there was a 12 percent improvement in prenatal care use and in low-birth-weight reduction, and yet for each of those there was no change from 1979 until 1988.

The Nation made zero progress whatsoever. As a result of that we had public health service objectives for the year 2000 released last week. We had to recycle the 1990 objectives. For prenatal care and low birth weight the objectives will remain exactly the same and give ourselves another decade to try to reach that goal.

Clearly, we know we can't reach that goal unless we make an investment such as we made—have begun to make through Medicaid and we need to continue for those other low income women.

Mr. Waxman. Thank you very much for the answer to that question. Mr. Gehring, this afternoon Dr. Wilensky, the HCFA administrator, will appear before this subcommittee. She will testify that the Bush administration cannot support the Frail Elderly Community Care Amendments. She will argue that this bill would increase Medicaid spending, expand Medicaid coverage to include many nonmedical social services, and duplicate the coverage that States can already provided under the current home and community-based waiver.

How would you respond?

Mr. Gehring. Well, Mr. Waxman, this bill might increase Medicaid spending modestly if the States exercise the option. It would expand Medicaid coverage to include some nonmedical social services. There has been systematic exclusion of Alzheimer's victims from both private and public insurance on the grounds that since there is no medical treatment and no medical cure, their care is custodial.

I have described to you how disabled these people are, how much care they require. They fall outside of the system today, and yet there are 4 million of these patients in the United States today and we are one of the only nations in the industrialized world that does not provide care for our elderly, care for the people that have made the taxes, worked hard, and through no fault of their own, because there is no prevention for this disease, find themselves in a situation where they need extensive care over an extended period of time.

Mr. WAXMAN. Well, suppose she says that is all well and good but what we are suggesting in this proposal is just going to duplicate what they can already get in the community home—the current home and community-based waiver. Why isn't that adequate?

Mr. GEHRING. Thirty-eight States have already applied for waivers and received waivers and spend money in this area. That tells you something about the prevalence of the need. This bill would reduce administrative hurdles for the States and legitimize process and encourage more States to provide help.

Mr. WAXMAN. And keep OMB from blocking those States that do want the ability to spend their money as well as get Federal matching funds?

Mr. GEHRING. That's right. It would allow the States to choose the priority.

Mr. WAXMAN. Thank you very much.

Mr. Jones, the administration doesn't like the community habilitation amendments anymore than it likes the frail elderly bill. Dr. Wilensky will argue that the Wxman-Tauke-Dingell bill would increase Medicaid spending, expand Medicaid coverage to include many nonmedical social services and duplicate the coverage the States can already provide under the community and home-based waiver.

How would you respond?

Mr. JONES. There are three questions. First, the costs will increase because there are estimates of up to 150,000 persons out there now who are not receiving services, but I would refer to the CBO estimates which we think are reasonable estimates of the expenditures that the disability community believes addresses the pressing needs.

The second question concerning the medical social services, these services are available and provided under the waiver now. Essentially, I note that under the waiver Medicaid is provided, it does provide rehabilitation and other services that help attain and maintain the highest independent and capacity for self-care.

The third question duplicating the coverage States concerned, this will not—the bill, H.R. 3934 will not duplicate but will provide additional services not available now under the waiver provisions.

Mr. WAXMAN. Thank you very much. Ms. McGuire, it probably wouldn't surprise you to learn that Dr. Wilensky will tell us this afternoon that the administration opposes the Medicaid AIDS and HIV Amendments. She will argue that it is inappropriate to establish Medicaid eligibility on the basis of a specific disease.

How would you respond?

Ms. MCGUIRE. Sounds like fairly predictable testimony you are going to hear this afternoon. I think the first thing I would say is if the system was not so convoluted in its inherent structure, we would not be having to require such a change.

Preventive health care, which is essentially what your proposal is, would be a reimbursable element of an appropriate continuum of care, and so this is our only option we are faced with. I mean obviously at a very individual level this is a humane, moral, and a responsible thing to be doing to be assuring that those who are poor are going to have the same opportunity for hope in terms of combating this disease that others do.

But even at a systematic level, we believe there is a valid reason for pursuing this course. People with AIDS and AIDS-related conditions are disproportionately filling our hospital wards, our public health clinics, our public health settings. By their presence and their intense utilization of services, they are having an impact on access to health care for other poor people who have different medical needs.

Preventing their deterioration is going to at least forestall for sometime and perhaps prevent the impending disaster we see in those settings. I would also finally point out that getting treatment to people earlier in the disease also provides an opportunity to intervene with them for purposes of behavior change, so that they can receive the information and support that they need to assure that they continue not to spread this disease.

In that respect, the treatment relationship becomes a real opportunity for both primary and secondary prevention, so we think that this is a model proposal and a necessary one as well as being a right and humane one.

Mr. WAXMAN. Thank you for your answer. Well, I want to thank each of you on this panel for your testimony today, and you know I agree with all you have said. I support these items of legislation. I think the arguments you have made are compelling, and I would hope maybe between now and 2 o'clock, Dr. Wilensky will have an opportunity to hear your responses and change her views. We will find out at 2 o'clock. Thank you very much.

Our next panel reflects the perspective of the States which finance about 45 percent of all Medicaid spending. Alicia Pelrine is the Group Director for Human Resources for the National Governors Association. Carol Taylor-Little is a State Representative from Colorado who is appearing on behalf of the National Conference of State Legislatures. Ray Hanley is the Director of the Arkansas Office of Medicaid Program, who represents the American Public Welfare Association, and James Toews is assistant administrator for development disabilities with the State of Oregon.

He is here on behalf of the National Association of State Mental Retardation Program Directors. I want to thank each of you for appearing today. Your complete statements will be in the record in full. Without objection, I would like to insert in the record at this point the full text of my August 17 letter to Governor Gardner to which Ms. Pelrine refers in her written statement.

[The information follows:]

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC, August 17, 1990.

Governor BOOTH GARDNER,
Chairman, National Governors' Association, Hall of the States,
Washington, DC.

DEAR GOVERNOR: Thank you for your letter of June 7 expressing your continuing concern about increasing Federal Medicaid mandates in general, and your specific opposition to the Medicaid Infant Mortality Amendments of 1990, H.R. 3931, and the Medicaid Child Health Amendments, H.R. 3932.

I regret that we have reached the point where the nation's Governors are joining with the Bush Administration in opposing modest, incremental improvements in the Medicaid program targeted to pregnant women and children. I would like to ask you to reconsider your opposition to these initiatives. In my view, there is simply no better investment that we as a Nation—the Federal government and the States—can make.

This same observation has been made by the National Academy of Sciences, the Office of Technology Assessment, and the National Commission to Prevent Infant Mortality. It was recently underscored by the Report of the White House Task Force on Infant Mortality in the United States (Draft, November 30, 1989). The Task Force, chaired by the Assistant Secretary for Health and representing the views of 10 departments and agencies of the Federal government and 6 offices within the Office of the President, found that "by applying the knowledge it already has, this country can prevent an additional 100,000 infant deaths and an estimated 100,000 disabling conditions in the newborn."

I know that States are concerned about the short-term fiscal implications of these two initiatives. But there is a broader, long-term national interest here, which the White House Task Force cogently articulates: "This country cannot afford its current infant mortality rate in economic or in human terms. The high economic cost of infant mortality is well documented, as is the cost-effectiveness of early prenatal care in reducing infant mortality and morbidity. For example, a 1985 study by the Institute of Medicine found that every additional dollar spent on prenatal care for certain high-risk women saved $3.38 in total costs of care for low-birthweight infants. The human costs of preventable infant mortality and morbidity in suffering, disability, lost productivity, and national pride are insupportable."

Much to your credit, you and the White House have recently adopted a set of national education goals designed to improve the nation's long-term productivity and competitiveness in a global marketplace. Among this goal is the readiness of children to start school. My concern is that children who begin life at low birthweight due to lack of prenatal care, or who develop avoidable impairments early in life due to the lack of preventive or primary care, will not be ready to start school. Of course, infants who die during the first year of life never make it to school. Again, the White House Task Force spells out the economic consequences of infant mortality: "Each infant death represents an estimated $380,000 in lost productivity (the present value of future lifetime earnings in 1985 dollars, using a 4 percent discount rate). Thus, if the United States could achieve the infant mortality rate of Massachusetts, the State with the lowest rate, it would realize $2.3 billion in increased productivity."

I am unwilling to forgo this investment in our nation's future. That's why I have joined with Representatives Cardiss Collins and Henry Hyde in sponsoring the Medicaid Infant Mortality Amendments, which would implement President Bush's campaign promise to phase-in Medicaid coverage for all pregnant women and infants with incomes below 185 percent of the Federal poverty level. That's why I have joined with Representatives Jim Slattery and George Miller in sponsoring the Medicaid Child Health Amendments, which would implement President Bush's campaign promise to phase-in Medicaid coverage for all children in families with incomes below 100 percent of poverty.

By full implementation in fiscal year 1993, the Infant Mortality Amendments will extend Medicaid coverage to an estimated 125,000 pregnant women and 88,000 infants at a total Federal and State cost of $227 million. The Child Health Amendments would reach an estimated 436,000 poor children by that year at a Federal and State cost of $190 million. Given the long-term economic and productivity gains, I consider these a superb investment for the Federal government and the States.

I want to stress that these initiatives are modest and incremental. These proposals do not attempt to cover all of the 31 to 37 million uninsured in this country. Taken together, these two provisions would increase projected Federal and State Medicaid outlays in fiscal year 1993 by only four-tenths of one percent (0.004). Finally, these eligibility expansions are not effective immediately. They are phased in to give States time to make the necessary budgetary adjustments. Although 15 States already cover pregnant women and infants with incomes below 185 percent, the Infant Mortality Amendments would give the remaining States until July 1, 1993, to reach that target. Under the Child Health Amendments, coverage would be extended, one year at a time, to all poor children who are now 7, until by September 30, 2001, all poor children under 18 would be covered. That's an 11 year phase-in.

I want to assure you that the Infant Mortality and Child Health Amendments are not part of some long-term strategy to address the nation's uninsured crisis by expanding Medicaid as it is currently structured. Instead, they are simply an effort to use an existing program to respond to an infant mortality and child health crisis that is now upon us. In my view, Medicaid is not the long-term answer to the crisis of the uninsured.

As the report issued recently by the NGA Subcommittee on Health makes clear, survey data suggest that "if the Medicaid program were not perceived to be part of an unpopular welfare system, there would be greater public support for expanding the coverage of low-income Americans." I have proposed that we create a new public program to provide basic health care coverage to those Americans who are not covered through their employers by Federalizing both the administration and the financing of the acute care portion of the Medicaid program. This would (1) extricate the program of health care for the uninsured from State and local welfare bureaucracies, (2) allow the establishment of uniform national eligibility, coverage, and payment rules, and (3) relieve States of the growing burden of financing hospital, physician, and other basic medical care for low-income families.

I applaud your interest in fundamental restructuring of our Nation's health care system, and I look forward to your recommendations, which I understand will become available next year. I hope that you will join me in urging the Congress to make available the Federal resources necessary to fund a new public program divorced from the welfare system to pay for basic health services for those Americans who do not have coverage through their employers.

However, I cannot agree with you that Congressional action on modest, incremental improvements in the Medicaid program must await a decision on fundamental reform. We—the Federal government and the States—simply cannot allow hundreds of thousands of low-income pregnant women and young children to go without preventive or primary services while we take the next several years to debate—and phase-in—a major restructuring of our financing and delivery system. As the White House Task Force on Infant Mortality concluded, quoting President Bush, "we must give our children a better start in the world [and] see that quality health services so critical for improving maternal and infant health will be available to all pregnant women and young children in our nation."

I look forward to working with you to reduce our Nation's infant mortality rate, to improve the health status of our children, and to address the crisis of the uninsured. With all best wishes, I am,

Sincerely,

Henry A. Waxman,
Chairman, Subcommittee on Health and the Environment.

Mr. Waxman. I would like to ask each of you, if you would, to limit your oral presentation to 5 minutes so that we can have time for questions. Ms. Pelrine, pull the microphone over. We would like to hear from you first.

STATEMENTS OF ALICIA PELRINE, GROUP DIRECTOR, HUMAN RESOURCES, NATIONAL GOVERNORS ASSOCIATION; CAROL TAYLOR-LITTLE, ON BEHALF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES; RAY HANLEY, CHAIRMAN, STATE MEDICAID DIRECTORS' ASSOCIATION OF THE AMERICAN PUBLIC WELFARE ASSOCIATION; AND JAMES D. TOEWS, ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE MENTAL RETARDATION PROGRAM DIRECTORS, INC.

Ms. Pelrine. Thank you, Mr. Chairman.

Appreciate the opportunity on behalf of the Governors to speak with you today about our perspective on the package of Medicaid expansions before the committee. I would reiterate something that you quite well know, Mr. Chairman, and that is that the Governors have a longstanding commitment to the provision of health care services to the most vulnerable of our population.

It was, in fact, the Governor's initiative back in 1986 that first suggested the delinking of Medicaid eligibility from AFDC eligibility for purpose of providing optional Medicaid coverage to pregnant women and children through the age of 18 who are at or below 100 percent of poverty.

This was an initiative that came out of the Governors' concerns with low-birth-weight babies and their impact on not only our fiscal condition but our human condition as well.

Prior to the implementation of last year's mandates covering pregnant women and children through the age of 6 to 13 percent of poverty, 44 States were providing coverage to 100 percent of poverty and 24 States were providing coverage up to 185 percent of poverty.

Forty-six States had dropped asset testing; 43 States were providing continuous eligibility. But States also recognize clearly that the question of access to health care services is not simply a question of providing someone with a Medicaid card, and so going beyond Congressional options, States have moved aggressively to provide streamlined eligibility procedures to do aggressive outreach to try to bring people who are eligible into the program and to do something about what in many cases is a woeful lack of providers who are willing to participate in the Medicaid program.

As you also well know, Mr. Chairman, Medicaid is not our only concern. Coming out of our Chicago meeting in 1989, when the Governors resolved to call on Congress and the administration to halt the enactment of any further Medicaid mandates for a period of 2 years while we came together to try to solve the long-term problem of universal access to care and controlling costs so that we might do that, the Governors put together a subcommittee of six.

That subcommittee reported to the full association this past July at our summer meeting in Mobile and laid out in that report which I believe you have a copy of there, suggested framework for what a program of providing universal access to quality health care services at affordable prices might look like.

Under the chairmanship of Governor Booth Gardner of Washington, who is now the chair of the association, that subcommittee has been expanded to a task force of 14 Governors, and those 14 Governors have been charged with the task of putting before the association a complete policy and plan for the provision of universal access to care in 1991.

And yet, we are back again today looking at Medicaid mandates, and that continues to trouble and concern us. State fiscal balances right now are the lowest since the recession of the early 1980's. In 1991 fully two-thirds of the States are in somewhere between moderate and severe fiscal difficulty. In 1990 State spending on Medicaid increased by 18.4 percent, and Medicaid is now consuming 12 percent of the State budget, and we would expect to spend an additional $2.3 billion on Medicaid in 1991 based on the last 3 years of Medicaid mandates.

As you also well know, Mr. Chairman, while the Federal Government has the opportunity to be more creative with how they play with deficit situations, States don't have that option. States are talking about real dollars and States have constitutional mandates to operate within a balanced budget, so the potential of additional Medicaid mandates this year in the context of some of the budget summit proposals which I haven't yet heard mentioned here this morning is of particular concern to us.

It is our understanding right now that seriously being considered alive and well is a proposal to lower the floor on Medicaid matching rates for those States who are currently at 50 percent match, to reduce or eliminate enhanced matches in both the Medicaid and the Child Support Enforcement program and to block grant administrative costs in the Medicaid program, and to increase costs to the Medicaid program by raising the cost of premiums and deductibles for Medicare beneficiaries, all of which has a significant impact on our ability to operate the program for the people who are currently enrolled in Medicaid.

We feel the same swings and shifts in the economy that you do, and we don't know where we will find the money that the Federal Government has been unable to find to fund new productions. Mr. Chairman, your leadership and your vision in this area is well recognized by the Governors.

They have appreciated your fighting with us and for us over the years to preserve and protect the Medicaid programs from unwarranted cuts. Your compassion for children is obvious. We understand your feelings about the urgency of this situation. We understand that you don't want to wait.

All we would say to you very quickly in concluding is that we have got a whole bunch of other concerns about children that we also have to fund with scarce State dollars, and all of those concerns for children are important from the gubernatorial perspective, so we would ask that you try to extend to us this year increased options for the Medicaid program.

Much of your package does involve increased options, or if that is not an option, then we would request or suggest that we might want to look at some additional Federal funding of those issues for children which we consider to be a major national priority. Thank you.

[The prepared statement of Ms. Pelrine follows:]

PREPARED STATEMENT OF ALICIA PELRINE, ON BEHALF OF THE NATIONAL GOVERNORS' ASSOCIATION

Good morning, Mr. Chairman, members of the committee. I am Alicia Pelrine, Group Director for Human Resources for the National Governors' Association. I appreciate the opportunity to talk with you today, on behalf of the nation's Governors, about the pending legislation to expand Medicaid to combat infant mortality, improve children's health, and enhance access to services for persons who are elderly, disabled, or have AIDS.

First, I want to reiterate that improving access to health services for the nation's low-income citizens has been and continues to be a high priority for the nation's Governors. It was the Governors who, in 1986, first proposed the delinking of Medicaid and Aid to Families with Dependent Children [AFDC] for the purpose of providing Medicaid coverage to pregnant women and children. That 1986 policy called for legislation to permit states to expand Medicaid programs to cover all pregnant women and children up to age 18 with family incomes below the poverty level. As optional Medicaid expansions were made available to states, most took swift advantage of the opportunity to expand health care coverage for pregnant women and children.

By January 1990, 44 states had taken advantage of the option to provide Medicaid eligibility to pregnant women and infants with family incomes below the poverty level and 24 states provided coverage for pregnant women and infants up to 185 percent of poverty. Additionally, 46 states had dropped asset testing for pregnant women and children and 43 states had opted for continuous eligibility for 60 days post-partum.

Because we recognize that real access to health care services is not simply a question of providing a Medicaid card, states have looked beyond congressional options for other ways to ensure that people get the services that positively impact their health. States have taken innovative approaches to ensuring access by streamlining their eligibility processes, aggressively reaching out to bring women and children into the program, and increasing provider participation to serve our clients. States have also tried to improve the health status of women and children by offering important nonmedical health services like home visits, nutritional counseling, care coordination, psychosocial services, and health education.

Beyond the immediate issue of Medicaid, however, is a much broader gubernatorial commitment to improving the health status of our citizens. As this committee is well aware, in July of 1989, the Governors appealed to Congress and the administration to halt the enactment of any further Medicaid mandates for a period of two years while we worked together to find long-term solutions to the twin problems of inadequate access to care and escalating health care costs that place care beyond the reach of so many.

Since that resolution, the Governors have moved aggressively to fulfill their commitment to seek solutions. Over the last year, a subcommittee of six Governors developed a framework for policy that seeks the goal of universal access to quality health care at affordable prices.

This past July, Governor Booth Gardner, the chairman of the National Governors' Association, expanded the subcommittee to a task force of 14 Governors who will put policy for universal access to health care before the full body of the association in 1991.

However, despite our efforts to resolve both the immediate problem of health care coverage for women and children and our longer range strategy to contribute to the national debate on universal access, the issue of additional Medicaid mandates continues to confront us.

The trend toward federal Medicaid mandates is particularly alarming as more and more states face budget shortfalls and the consequences of adverse changes in the economy. A March survey conducted by the National Association of State Budget Officers [NASBO] revealed that current state fiscal balances are lower than at any time since the recession of the early 1980s. For fiscal 1991, approximately two-thirds of the states are in some degree of fiscal difficulty. Meanwhile, state spending on Medicaid continues to rise rapidly. In 1990, state Medicaid spending increased by 18.4 percent and Medicaid now consumes a recordbreaking 12 percent of state spending, second only to elementary and secondary education.

Additionally, it is estimated that state spending will increase at least an additional $2.5 billion in fiscal 1991 as a result of Medicaid mandates enacted over the last three years.

States simply cannot afford another year of mandates. Unlike the federal government, states cannot run a budget deficit. Every mandated dollar that we spend is a real dollar that has to be taken from another program. The Governors have had to make very difficult choices in a wide array of health and human services programs to meet the mandates enacted in the past few years. States are now struggling to do more with less. Additional mandates at this time will do more ham than good to current programs.

And this year, our concern about state budgets and additional mandates is heightened by proposals being considered in federal deficit reduction discussions. Among the budget proposals under consideration is a series of Medicaid changes that would significantly increase state costs and shift federal responsibility to the states. Included are such ideas as lowering the floor on federal Medicaid matching rates to 45 percent from 50 percent; eliminating enhanced matching rates and capping reimbursement for administrative costs; and increasing beneficiary payments for Medicare Part B benefits.

It is almost inconceivable to the Governors that Congress could be talking seriously about these kinds of deficit reduction proposals while at the same time attempting to force additional program requirements on the states.

State government is feeling the impact of the same economic swings and strains as the federal government. It is incongruous for the federal government to assume states can find savings where it has not been able to, or that states can assume significant new program costs when state budgets are being cut back.

Mr. Chairman, under your leadership this committee has helped enact sweeping changes in the Medicaid program. The nation's Governors have strongly supported many of your initiatives as they provided states with needed flexibility to expand and develop state Medicaid plans to best meet the needs of low-income individuals and families. In recent years, however, this year's option has become next year's mandate without regard to a state's ability to finance the mandate or the impact the mandate will have existing state expansion plans.

We do continue to support optional expansions to the Medicaid program and, in particular, believe that the next logical step is for Congress to provide states the option to expand Medicaid coverage to children through the age of 18 who are below the federal poverty level. This option would continue to move federal policy in the direction of linking Medicaid eligibility to poverty-related status rather than the receipt of welfare assistance. At the same time, it would offer states the opportunity to manage and plan program expansions in a fiscally responsible manner.

Mr. Chairman, last month you sent Governor Gardner a thoughtful and compelling letter outlining your reasons for not wanting to wait for agreement on a plan to provide universal access to health care before offering assistance to the thousands of women and children whose health care needs could be met now through the Medicaid program. The overwhelming sense of compassion you feel for these women and children shone through your letter.

We agree with you that the need is there; that it is real and it is urgent. But while you focus your attention on just one aspect of the needs of children and their families, we must focus our attention and our resources on the multiple needs of children and their families. The Governors must make allocation decisions on real dollars and they must allocate scarce dollars among a wide variety of needs—the needs of children to be fed and housed, to be protected from abuse and neglect, to be educated, and to be kept safe from drugs and crime.

At this time, the states simply cannot afford additional mandates without further cutting back on other vital programs. We have been stretched beyond our capacities to afford another year of mandates. Further, we firmly believe that to continue this way diverts both attention and resources form solving the underlying problem of inadequate access and runaway costs that plague our nation's health care system.

In reaching our mutual goal of a healthier citizenry, we appreciate the opportunity to work with this committee to fashion an optional package of Medicaid expansions that we could all support. If Congress is firmly committed to moving forward with Medicaid expansions this year, we ask that they be options or that they be financed by the federal government until a universal access plan is agreed upon. We share your goals, but at the same time must protect our states from collapsing.

Thank you again for allowing me to appear before this committee. The Governors and their staffs look forward to working with you as we work toward providing universal access to health care.

Mr. WAXMAN. Thank you very much. Ms. Taylor-Little.

STATEMENT OF CAROL TAYLOR-LITTLE

Ms. TAYLOR-LITTLE. Thank you, Mr. Chairman, good morning.

I want to tell you how much I appreciate having the opportunity to be here today and discuss with you the National Caucus of State Legislatures legislative priorities.

I think it is fair to say that we are less than enthusiastic about your 1990 legislative package, not because we oppose improved health care access, but because our plates are already full just implementing the existing mandates and because our resources are already stretched woefully thin.

Because you already have my prepared written comments, let me just highlight several things that I think are the States' critical concerns. While the expenditures do vary widely from State to State, Medicaid is second only to education as a major component of State general fund expenditures. Medicaid is consuming larger and larger portions of State budgets.

While State budget analysts predicted that average Medicaid expenditures would grow by approximately 10 percent between fiscal years 1990 and 1991, they actually increased by almost 25 percent.

Now, while our resolve to expand access and to provide quality health care services is strong, our resources are diminishing. The escalating health care costs and the unanticipated increases in caseload account for perhaps half of these costs, but much of the remainder can be directly attributed to the recently enacted Federal Medicaid mandates.

Last year States increased taxes more than any other year since 1983. The National Economic slowdown currently underway will exacerbate the problem of increasing Medicaid caseloads and decreased tax base. If the economy remains slow for a prolonged period, the costs are certain to rise.

My three main points are, one, we strongly urge you to refrain from additional mandates. At this point each additional mandate becomes an obstacle in our efforts to provide expanding access to our Medicaid beneficiaries.

We have limited resources, limited infrastructure to implement these requirements; two, what we do need is an opportunity to deal with the current mandates; and, three, to maintain as much State flexibility as possible.

In the next few minutes I will briefly share with you what NCSL's priorities are. We urge you to support passage of H.R. 4181, the Medicaid State Share Protection Act of 1990 sponsored by your colleague, Congressman Jim Cooper of Tennessee.

We do believe that all voluntary contributions and all State taxes should continue to qualify for Federal matching funds. State revenue raising authority cannot and should not be conditioned on Federal statute or regulation. To suggest otherwise runs counter to the principles of federalism and represents an unwarranted intrusion into a basic State function.

We believe that this is an important piece of legislation. We urge you to support passage of this legislation this year. Also, high on our list of priorities is the enactment of technical and perfecting amendments to the nursing home provisions of the Omnibus Reconciliation Act of 1987.

We are particularly concerned about the lack of timely and adequate guidance we are receiving from the health care financing authority. There are major problems here. We urge you to work with us to clarify so we can move forward with implementation.

NCSL was delighted to see S. 2240, the Ryan White Comprehensive AIDS Resources Emergency Act, signed into law. We believe that this legislation should be a high priority with respect to funding for new initiatives in 1990. If we are to continue with Medicaid programs, States must have options.

NCSL continues to support the development and implementation of Medicaid options that provide sufficient State flexibility to design programs that are suited to the citizens of our States.

All too often even the optional programs are so prescriptive that they discourage State participation. Last month during NCSL in Nashville, we adopted a new policy on access, and it does call for the development of a national strategy for health care reform that guarantees basic health care services to all Americans.

I would like to submit a copy of this policy for the record.

We are as frustrated as you are with the inadequacy of the Medicaid program specifically and the inadequacies of our health care system in general. When enacted in 1965 Medicaid was limited, and it has grown to be a billion dollar imperfect instrument, and we can't afford it. We urge you to stop incrementally letting out the seams and to instead go forward with serious effort to address the inadequacies of our existing health care system.

We believe that systematic change is needed and that a piecemeal approach primarily directed at Medicaid will not ultimately provide the universal coverage we seek.

We must be the partners, Congress and the States, in the development of a national health care strategy. States must play an integral role in both the development and implementation of the strategy. We believe that States are the laboratories, the incubators and much is happening for the most part without Federal support.

We have State and local health care programs for the medically indigent, risk pools, study commissions, groups and task forces, demonstration entrants, Robert Woodson Foundation and other private sector groups. We have one in Colorado called SCOPE that is exceedingly effective. Last but certainly not least let me just discuss waivers.

NCSL firmly believes that where legislation to expand access to care is enacted by the legislature and signed by law by the Governor, that that law should be granted necessary waivers. We need your help. We would hope that you will not stand in the way of progress.

Help us to develop an expedited waiver process. We cannot do it alone. We look forward to working with you, the Congress, in developing a universal health care access program. Thank you.

[Testimony resumes on p. 131.]

[The prepared statement of Ms. Taylor-Little follows:]

TESTIMONY OF

REPRESENTATIVE CAROL TAYLOR-LITTLE

ON BEHALF OF THE

NATIONAL CONFERENCE OF STATE LEGISLATURES

CHAIRMAN WAXMAN AND DISTINGUISHED MEMBERS OF THE SUBCOMMITTEE:

I AM CAROL TAYLOR-LITTLE, STATE REPRESENTATIVE FROM COLORADO. THIS MORNING I AM SPEAKING ON BEHALF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES (NCSL) WHERE I SERVE AS A VICE-CHAIR OF THE HEALTH COMMITTEE. I AM MAJORITY CAUCUS CHAIR OF THE COLORADO HOUSE OF REPRESENTATIVES AND SERVE AS CHAIR OF THE JOINT REVIEW COMMITTEE FOR THE MEDICALLY INDIGENT.

IT IS CERTAINLY A PLEASURE TO HAVE THE OPPORTUNITY TO DISCUSS NCSL PRIORITIES WITH SUCH A DISTINGUISHED PANEL WHOSE COMMITMENT TO EXPANDING ACCESS TO HEALTH CARE IS WELL KNOWN AND RESPECTED BY STATE LEGISLATORS NATIONWIDE. NCSL SHARES YOUR CONCERN AND COMMITMENT TO PROVIDING AFFORDABLE, QUALITY HEALTH CARE TO ALL AMERICANS.

I THINK IT IS FAIR TO SAY THAT WE ARE LESS THAN ENTHUSIASTIC ABOUT YOUR 1990 LEGISLATIVE PACKAGE. NOT BECAUSE WE OPPOSE EXPANDED HEALTH CARE ACCESS, BUT BECAUSE OUR PLATES ARE FULL IMPLEMENTING EXISTING MANDATES AND BECAUSE OUR RESOURCES ARE ALREADY STRETCHED WOEFULLY THIN.

STATE FISCAL CONDITIONS

WHILE EXPENDITURES VARY WIDELY FROM STATE TO STATE, MEDICAID IS SECOND ONLY TO EDUCATION AS A MAJOR COMPONENT OF STATE GENERAL FUND EXPENDITURES. HEALTH CARE EXPENDITURES REPRESENT APPROXIMATELY 20 PERCENT OF STATE GENERAL FUND EXPENDITURES, WITH MEDICAID REPRESENTING A LITTLE MORE THAN HALF OF THAT AMOUNT.

WHILE STATE BUDGET ANALYSTS PREDICTED THAT AVERAGE MEDICAID EXPENDITURES WOULD GROW BY APPROXIMATELY 10 PERCENT BETWEEN FY 1990 TO FY 1991, ACTUAL MEDICAID EXPENDITURES INCREASED BY ALMOST 25 PERCENT. IN TWENTY STATES THE INCREASE IN MEDICAID EXPENDITURES EXCEEDED 20 PERCENT.

WHILE OUR RESOLVE TO EXPAND ACCESS AND TO PROVIDE QUALITY HEALTH CARE SERVICES TO ALL IS STRONG, OUR RESOURCES ARE DIMINISHING. ESCALATING HEALTH CARE COSTS AND UNANTICIPATED INCREASES IN CASELOAD ACCOUNT FOR PERHAPS HALF OF THESE INCREASED COSTS. MUCH OF THE REMAINDER CAN BE DIRECTLY ATTRIBUTED TO RECENTLY ENACTED FEDERAL MEDICAID MANDATES.

LAST YEAR STATES INCREASED TAXES MORE THAN ANY YEAR SINCE 1983. WHILE STATES RAISED A BROAD ARRAY OF TAXES, MANY STATES RAISED PERSONAL INCOME, CORPORATE INCOME, SALES AND USE TAXES, THE HEAVY LIFTERS OF TAXING OPTIONS. RAISING TAXES ARE NEVER EASY.

SOMETHING I NEED NOT TELL ANY OF YOU. STATE LEGISLATORS WOULD NOT RAISE THESE TAXES IF OTHER OPTIONS WERE AVAILABLE. THIS IS AN IMPORTANT INDICATION OF THE FISCAL CLIMATE IN THE STATES.

THE ECONOMIC SLOW DOWN CURRENTLY UNDERWAY WILL ONLY EXACERBATE THIS PROBLEM BY INCREASING OUR MEDICAID CASELOAD AND DECREASING OUR TAX BASE AT THE SAME TIME. IF THE ECONOMY REMAINS SLOW FOR A PROLONGED PERIOD, THE ESTIMATED COSTS OF YOUR 1990 PROPOSED MANDATES WILL CERTAINLY RISE.

WE STRONGLY URGE YOU TO REFRAIN FROM ADDITIONAL MANDATES. AT THIS POINT EACH ADDITIONAL MANDATE BECOMES AN OBSTACLE TO US IN OUR EFFORTS TO PROVIDE EXPANDED ACCESS AND QUALITY CARE TO OUR MEDICAID BENEFICIARIES. WE HAVE LIMITED RESOURCES, LIMITED INFRASTRUCTURE AND LIMITED PERSONNEL TO IMPLEMENT THESE REQUIREMENTS.

WHAT WE DO NEED IS AN OPPORTUNITY TO FULLY AND ADEQUATELY IMPLEMENT THE MANDATES YOU HAVE ALREADY ENACTED. OUR PRIORITY NOW IS TO FULLY IMPLEMENT THESE MANDATES, TO SUSTAIN AND IMPROVE THE SERVICES WE CURRENTLY PROVIDE, TO MAINTAIN AS MUCH STATE FLEXIBILITY AS POSSIBLE, AND TO PROTECT OUR ABILITY TO RAISE STATE RESOURCES TO EXPAND ACCESS TO HEALTH CARE SERVICES. IN THE NEXT FEW MINUTES, I WILL BRIEFLY SHARE WITH YOU NCSL'S LEGISLATIVE PRIORITIES.

VOLUNTARY CONTRIBUTIONS AND PROVIDER-SPECIFIC TAXES

NCSL URGES YOU TO SUPPORT PASSAGE OF H.R. 4181, THE MEDICAID STATE SHARE PROTECTION ACT OF 1990, SPONSORED BY YOUR COLLEAGUE CONGRESSMAN JIM COOPER OF TENNESSEE. AS YOU KNOW, ON FEBRUARY 9, 1990, THE HEALTH CARE FINANCING ADMINISTRATION (HCFA) PUBLISHED PROPOSED REGULATIONS IN THE FEDERAL REGISTER THAT WOULD, IF MADE FINAL, SEVERELY RESTRICT STATE'S USE OF VOLUNTARY CONTRIBUTIONS AND PROVIDER-SPECIFIC TAXES AS SOURCES OF THE STATE SHARE OF MEDICAID EXPENDITURES.

WE BELIEVE THAT ALL VOLUNTARY CONTRIBUTIONS AND ALL STATE TAXES SHOULD CONTINUE TO QUALIFY FOR FEDERAL MATCHING FUNDS. STATE REVENUE RAISING AUTHORITY CANNOT AND SHOULD NOT BE CONDITIONED ON FEDERAL STATUTE OR REGULATION. TO SUGGEST OTHERWISE RUNS COUNTER TO THE PRINCIPLES OF FEDERALISM AND REPRESENTS AN UNWARRANTED INTRUSION INTO A BASIC STATE FUNCTION.

CURRENTLY SEVEN STATES (ALABAMA, CALIFORNIA, FLORIDA, GEORGIA, OHIO, TENNESSEE AND TEXAS) ARE USING VOLUNTARY CONTRIBUTIONS OR PROVIDER-SPECIFIC TAXES TO ENHANCE THEIR MEDICAID PROGRAMS. IN ADDITION, A NUMBER OF STATES ARE CONSIDERING THIS STRATEGY, BUT HAVE DELAYED ACTION BECAUSE THEY ARE CONCERNED ABOUT THESE PROPOSED REGULATIONS.

IN THE PAST, THIS HCFA PROPOSAL HAS BEEN HALTED BY A

CONGRESSIONALLY IMPOSED ONE YEAR MORATORIUM ON THE REGULATIONS. WE BELIEVE IT IS TIME TO PERMANENTLY ADDRESS THIS ISSUE. FOR THIS REASON WE ARE PLEASED THAT CONGRESSMAN COOPER AND SENATOR GRAHAM OF FLORIDA HAVE INTRODUCED LEGISLATION TO STOP THESE REGULATIONS FROM GOING INTO EFFECT. WE URGE YOU TO SUPPORT PASSAGE OF THIS LEGISLATION THIS YEAR.

TECHNICAL AND PERFECTING AMENDMENTS TO OBRA 1987

ALSO HIGH ON OUR LIST OF PRIORITIES IS THE ENACTMENT OF TECHNICAL AND PERFECTING AMENDMENTS TO THE NURSING HOME REFORM PROVISIONS OF THE OMNIBUS RECONCILIATION ACT OF 1987. WE ARE PARTICULARLY CONCERNED ABOUT THE LACK OF TIMELY AND ADEQUATE GUIDANCE WE ARE RECEIVING FROM THE HEALTH CARE FINANCING ADMINISTRATION.

WE URGE YOU TO EXTEND THE CUT-OFF DATE FOR THE ENHANCED FEDERAL MATCHING FUNDS FOR NURSE AIDE TRAINING FROM JUNE 30, 1990 TO OCTOBER 1, 1991, AND TO CLARIFY THE PROVISION THAT ENTITLES STATES TO RECEIVE FEDERAL MATCHING FUNDS AT THE SERVICE MATCHING RATE AS OPPOSED TO THE ADMINISTRATIVE MATCHING RATE. FINALLY, THERE ARE MANY PROBLEMS WITH THE PREADMISSION SCREENING AND RESIDENT REVIEW REQUIREMENTS (PASSAR). WE URGE YOU TO WORK WITH US TO CLARIFY THESE ISSUES SO THAT WE CAN MOVE FORWARD ON FULL IMPLEMENTATION.

GIVEN THE IMPRECISE NATURE OF THE CURRENT REGULATORY

GUIDELINES, STATES REMAIN UNABLE TO MAKE A REALISTIC ASSESSMENT OF COSTS OR THE VALUE ADDED TO DIRECT PATIENT CARE. REGARDLESS, THE ACT REQUIRES STATES TO IMPLEMENT THE MANDATED CHANGES BY OCTOBER 1, 1990. WE FIND THIS REQUIREMENT TROUBLING AND FRUSTRATING. WE BELIEVE THAT IN THE END IT WILL PROVE BOTH COSTLY TO THE STATES AND DISRUPTIVE TO PATIENTS AND PROVIDERS.

IN LIGHT OF OUR LIMITED RESOURCES AND THE MANY PROGRAMS AND SERVICES COMPETING FOR THESE DOLLARS, WE FIND IT INCREDIBLE THAT YOU WOULD RATHER SEE STATES GO FORWARD WITHOUT GUIDANCE, THAN TO WAIT UNTIL THE REGULATORY STRUCTURE IS IN PLACE.

RYAN WHITE COMPREHENSIVE AIDS RESOURCES EMERGENCY ACT

NCSL WAS DELIGHTED TO SEE S. 2240, SIGNED INTO LAW. WE BELIEVE THAT THIS LEGISLATION SHOULD BE A HIGH PRIORITY WITH RESPECT TO FUNDING FOR NEW INITIATIVES IN 1990.

MEDICAID OPTIONAL SERVICES

IF WE ARE TO CONTINUE WITH THE MEDICAID PROGRAM, STATES MUST HAVE OPTIONS. NCSL CONTINUES TO SUPPORT THE DEVELOPMENT AND IMPLEMENTATION OF MEDICAID OPTIONS THAT PROVIDE SUFFICIENT STATE FLEXIBILITY TO PERMIT US TO DESIGN PROGRAMS BEST SUITED TO THE CITIZENS IN OUR STATES. ALL TOO OFTEN EVEN THE OPTIONAL PROGRAMS ARE SO PROSCRIPTIVE THAT THEY DISCOURAGE STATE PARTICIPATION.

HEALTH CARE REFORM

LAST MONTH DURING THE NCSL ANNUAL MEETING IN NASHVILLE, TENNESSEE, THE CONFERENCE ADOPTED A NEW POLICY ON ACCESS TO HEALTH CARE. THIS POLICY CALLS FOR THE DEVELOPMENT OF A NATIONAL STRATEGY FOR HEALTH CARE REFORM THAT GUARANTEES BASIC HEALTH CARE SERVICES TO ALL AMERICANS. I WOULD LIKE TO SUBMIT A COPY OF THIS POLICY FOR THE RECORD.

STATES ARE AS FRUSTRATED AS YOU ARE WITH THE INADEQUACY OF THE MEDICAID PROGRAM SPECIFICALLY AND THE INADEQUACIES OF OUR HEALTH CARE SYSTEM IN GENERAL. EVEN IF STATES COULD AFFORD TO PROVIDE THE MAXIMUM COVERAGE PERMITTED UNDER THE MEDICAID PROGRAM, THERE WOULD CONTINUE TO BE A SUBSTANTIAL NUMBER OF UNINSURED INDIVIDUALS. THE MEDICAID PROGRAM WAS NOT DESIGNED TO SERVE ALL THE POOR OR ALL THE UNINSURED. WHEN ENACTED IN 1965, MEDICAID WAS A VERY LIMITED PROGRAM. IT HAS GROWN TO BE AN IMPERFECT INSTRUMENT FOR PROVIDING HEALTH CARE TO OUR NATION'S POOR AND ITS 32 MILLION OR MORE UNINSURED INDIVIDUALS.

WE URGE YOU TO STOP INCREMENTALLY LETTING OUT THE SEAMS OF THE MEDICAID PROGRAM AND TO INSTEAD GO FORWARD WITH A SERIOUS EFFORT TO ADDRESS THE INADEQUACIES OF OUR EXISTING HEALTH CARE SYSTEM. WE BELIEVE THAT SYSTEMIC CHANGE IS NEEDED AND THAT A PIECEMEAL APPROACH, PRIMARILY DIRECTED AT THE MEDICAID PROGRAM, WILL NOT ULTIMATELY PROVIDE THE UNIVERSAL COVERAGE

WE SEEK. WE LOOK FORWARD TO WORKING WITH YOU SIDE-BY-SIDE IN THE DEVELOPMENT OF A NATIONAL HEALTH CARE STRATEGY. STATES MUST PLAY AN INTEGRAL ROLE IN BOTH THE DEVELOPMENT AND IMPLEMENTATION OF A NATIONAL HEALTH CARE STRATEGY.

STATE ACTIONS

IN 1990, 33 STATES HAVE SOME KIND OF STATE OR STATE/LOCAL HEALTH CARE PROGRAM FOR THE MEDICALLY INDIGENT; 24 STATES HAVE RISK POOLS FOR THE MEDICALLY UNINSURABLE; 12 STATES HAVE STUDY COMMISSIONS, INTERIM STUDY GROUPS AND TASK FORCES CHARGED WITH THE RESPONSIBILITY TO DEVELOP A PLAN TO ADDRESS THE PLIGHT OF THE UNINSURED IN THE STATE. THESE PROGRAMS, FOR THE MOST PART, RECEIVE NO FEDERAL SUPPORT. IN ADDITION, THERE ARE A NUMBER OF ONGOING PROJECTS SPONSORED BY THE ROBERT WOOD JOHNSON FOUNDATION AND OTHER PRIVATE SECTOR GROUPS THAT HOLD PROMISE IN DEVELOPING USEFUL PUBLIC/PRIVATE PARTNERSHIP MODELS FOR ADDRESSING THE HEALTH CARE AND LONG TERM CARE NEEDS OF BOTH THE UNINSURED AND THE ELDERLY.

WHILE RELATIVELY LITTLE IS HAPPENING HERE IN WASHINGTON, WITH THE EXCEPTION OF THE CONTINUED ENACTMENT OF FEDERAL MEDICAID MANDATES, STATES HAVE BEEN EXTREMELY CREATIVE AND INNOVATIVE IN DEVELOPING AND DESIGNING PROGRAMS TO EXPAND HEALTH CARE COVERAGE. AS STATES CONTINUE TO DEVELOP AND ENACT INTO LAW, CUTTING EDGE, INNOVATIVE PROGRAMS DESIGNED TO EXPAND HEALTH CARE COVERAGE, WE WILL NEED YOUR SUPPORT AND ASSISTANCE TO

MAKE OUR LEGISLATIVE PROPOSALS REAL PROGRAMS.

AS YOU KNOW, THE MORE SWEEPING THE STATE PROPOSAL, THE MORE LIKELY IT WILL REQUIRE FEDERAL MEDICAID WAIVERS OR OTHER FEDERAL LEGISLATIVE ACTION TO MAKE IMPLEMENTATION POSSIBLE. NCSL FIRMLY BELIEVES THAT WHERE LEGISLATION TO EXPAND ACCESS TO CARE OR THE AVAILABILITY OF LONG TERM CARE SERVICES IS ENACTED BY THE LEGISLATURE AND SIGNED INTO LAW BY THE GOVERNOR, THAT THE CONGRESS SHOULD FACILITATE THE IMPLEMENTATION OF THAT LAW BY GRANTING THE NECESSARY WAIVERS.

WE WOULD HOPE THAT YOU WILL NOT STAND IN THE WAY OF PROGRESS, BY DENYING STATES THE OPPORTUNITY TO TRY OUT NEW IDEAS. WE WOULD LIKE TO WORK WITH YOU TO DEVELOP AN EXPEDITED WAIVER PROCESS THAT WOULD MAKE IT EASIER FOR STATES TO IMPLEMENT INNOVATIVE STATE HEALTH INITIATIVES.

WE BELIEVE THAT CONGRESSIONAL SUPPORT FOR STATE PILOT DEMONSTRATION PROJECTS THAT TEST INNOVATIVE AND CREATIVE WAYS OF EXPANDING ACCESS TO HEALTH CARE AND LONG TERM CARE MAY ULTIMATELY HELP PAVE THE WAY FOR THE DEVELOPMENT OF A HEALTH CARE REFORM STRATEGY THAT WORKS, ONE THAT IS BASED ON TESTED AND SUCCESSFUL PROGRAMS.

WHILE WE FULLY SUPPORT STATE INITIATIVES TO EXPAND ACCESS TO CARE, WE KNOW THAT STATES CANNOT REFORM THE HEALTH CARE SYSTEM ALONE. HEALTH CARE REFORM MUST BE DONE IN A PARTNERSHIP WITH ALL LEVELS OF GOVERNMENT, THE PRIVATE SECTOR, AND CONSUMERS. WE LOOK FORWARD TO WORKING CLOSELY WITH YOU AS WE SEEK CONSENSUS ON A STRATEGY TO PROVIDE HEALTH CARE TO ALL AMERICANS.

I THANK YOU FOR THIS OPPORTUNITY TO SHARE OUR THOUGHTS WITH YOU AND WOULD BE HAPPY TO ANSWER ANY QUESTIONS YOU MAY HAVE.

National Conference of State Legislatures

OFFICIAL POLICY

HEALTH

ACCESS TO HEALTH CARE

The growing crisis of Americans without basic health care demands the immediate development of a national health care reform strategy. While the United States has the most technologically advanced health care system in the world, soaring health care costs, increasing health insurance premiums, and shifting power structures in the managerial and provider sectors of the health care industry have profoundly affected the overall health care environments.

Steady increases in health care spending have paralleled steady increases in the proportion of uninsured individuals. Millions cannot afford basic health care and at least an additional twenty percent are "underinsured," whereby a major illness would cause financial ruin. Health benefits for many insured workers have been eroded, while many other employers no longer offer any health care benefits.

The National Conference of State Legislatures is committed to developing a national health care reform strategy that will guarantee basic health care services for all Americans. NCSL believes that any national strategy shall include a strong role for states. States must play an integral role in the development and implementation of a national health care reform strategy. A national strategy for health care reform should include the following components:

Basic Benefit Package

A basic benefit package, to which everyone is entitled must be developed. Primary care and preventive services should be emphasized.

Equitable Financing Mechanism

The source of funding for health care reform should be progressive, broad-based, and have potential for growth. Financial support for the program should be shared by government, the private sector and individuals according to their ability to pay.

Health Care Cost Containment and Quality Assurance

Health care cost containment and quality assurance must be an integral part of any health care reform proposal. Current components of the health care system, such as costs for direct services, administration, utilization review and quality assurance must be reviewed and evaluated to facilitate the identification of those measures that are most effective in both containing costs and maintaining quality of care.

The quality assurance program will help to ensure that each individual that enters the health care system receives appropriate, cost effective care. The quality assurance program should include: (l) national practice guidelines and standards of care; (2) enhanced data collection to support quality assurance activities; (3) enhanced and improved local review organizations to assess quality; and (4) continued federal support for medical outcomes and effectiveness research and other efforts to promote quality assurance, and technical assistance to states and local review organizations.

Action Plan

Important first steps have been taken at the federal level to explore ways to extend health care coverage to all Americans. NCSL urges the federal government to continue these efforts and to join with the states as partners to develop and implement health care reform. In addition to the activities of federal commissions and task forces, NCSL urges the Congress to hold hearings on health care reform and to look closely at innovative state models.

Access to Health Care

At the same time, NCSL believes that all Americans should have access to quality health care services, and is committed to a continuing effort to improve our existing health care system and to serve as many people as possible in it. In the absence of a national effort to reform the health care system, the National Conference of State Legislatures urges the Congress and the Administration to address these priority issues to improve access to health care.

Medicaid

NCSL urges Congress to increase the number and range of optional services authorized under the Medicaid program, but to refrain from imposing any additional mandated coverages. *NCSL* opposes measures that would prohibit states from developing innovative programs and financing mechanisms designed to extend health care coverage to more individuals. NCSL urges the Congress and the Administration to expand the demonstration authority under the Medicaid program and to develop an expedited waiver process to enable states to more effectively continue in the role as laboratories for innovation. Finally, NCSL urges the Congress to continue to provide funds to the U.S. Department of Health and Human Services for technical assistance to states to assist in efforts to get the most from limited resources and to share information on successful strategies to expand health care services.

Discretionary Health Programs

NCSL urges the Congress to fully fund discretionary health programs that supplement state and local health care programs and that support efforts to address the needs of special populations. The Preventive Health Block Grant, the Maternal and Child Health Block Grant, the Alcohol, Drug Abuse, and Mental Health Block Grant, AIDS funding, and special infant mortality initiatives funded by the U.S. Department of Health and Human Services are NCSL priorities.

Federally Mandated Health Care Programs

NCSL urges the Congress to reject proposals that would require states to enact and implement risk pools or similar health care programs or that would preempt existing health care programs and replace them with a uniform federal program, unless the proposal is part of a national health care reform proposal supported by the Conference. At a minimum, if a federally mandated program is enacted, states with similar existing programs should be grandfathered in.

Employee Retirement Income Security Act of 1974 (ERISA)

NCSL urges the Congress to enact legislation extending state regulatory authority to include self-insured plans, authority currently precluded by ERISA. This authority would provide states with a broader financing base with which to fund programs to expand health care coverage. At a minimum, NCSL believes that states, that enact legislation extending health care services to uninsured persons and others with inadequate health care coverage, should be granted an exemption if requested.

Health Education

NCSL urges the Congress to increase efforts within the U.S. Department of Health and Human Services to support the promotion of healthy lifestyles and to assist people in becoming prudent purchasers of health care services.

Mr. WAXMAN. Thank you very much. Mr. Hanley.

STATEMENT OF RAY HANLEY

Mr. HANLEY. Thank you, Mr. Chairman.

Let me thank you for the opportunity to be here today on behalf of the Nation's Medicaid directors and APWA to speak to some of the concerns we have all heard today about Medicaid expansion and access to health care in general.

It is important that you, the committee, and all of us understand the States share these concerns.

We are very aware of the plight of the uninsured, the underinsured. I know I have a half million people in my own State of Arkansas that have no health insurance. It is State flexibility in our view that is the key, has been and will continue to be in dealing with these problems.

The State's view Medicaid expansion options as the key to continuing this innovation. We, on the other hand, view the expansion mandates with growing concern.

The physical constraints are going on States. We have already heard that. State agencies on the other hand do not oppose mandates simply because they do not wish to serve the poor. Quite to the contrary, regarding Medicare, the majority of the States have already elected to cover pregnant women and infants up to the poverty level prior to the mandate to do so.

Nineteen States have already moved to cover the population and incomes between 100 and 185 percent of poverty prior to the OBRA 1989 mandate to over up to 133 percent of poverty. Twenty States already covered older children up to the existing poverty level prior to the mandate.

If you look at the record, over 18 months, given the opportunity, the time to budget and plan, the majority of the States sees the options. But the key is to do it through options, to give the States time. OBRA 1989, for instance, caught my State in the middle of a biannual budget cycle, we had very little time to implement.

It has created some real problems. Federal mandates for the expansion of the programs during times of limited State resources can and do meet, but difficult and very real choices must be made regarding coverage and all parts of the program.

In Arkansas, there are $68 million worth of analyzed Federal mandates that have come to us over the last 4 years. We recently eliminated $37 million worth of services, including our adult mentally needy, adult mental services, and there are similar situations across the board.

Alabama's reduced physician visits, hospital days, South Carolina has reduced the number of covered prescriptions or are planning to. Oklahoma reduced outpatient prescriptions from three to one. Medicaid continues to consume 12 percent of the State budget nationally, second only to education.

The growth rate in the face of more mandates is going to go up from there. And beyond Medicaid expansion, APWA has some proposals to seriously reform health care access. We will be glad to give you details of that later. The State Medicaid directors support this and believe that Medicaid mandates, maybe date expansion such as those before the committee are simply no longer politically expedient from the State perspective.

The APWA health care plan, they represent the input of staking service administrators, we have developed a series of policy proposals for both acute care and long-term care. Long-term care patterned off a social insurance model, it allows an option for commercial insurance. Long-term care, most of us know it takes a lot of the Medicaid dollars. We may not know that 40 percent of State Medicaid budgets on average go to long-term care.

The important part of these proposals developed by input from human services administrators is that they represent a consensus. It is time to move away from the means of tested welfare programs, means tested, and to allow access for the growing number of people that are currently having access problems, no insurance, losing insurance.

Improving Medicaid, again, we feel like the key is options. We support the option to cover nonmedical residential subsidiaries treatment for pregnant women. We know what it costs to treat crack babies and those that are born addicted to alcohol and other substances. We support broadly defined options to permit coverage of older children with up to 185 percent of poverty. We support the option of continuous eligibility for infants for a period of 1 year. We support the option to drop the assets test.

Another matter I want to urge the committee and Congress to protect the current program from erosion due to HCFA efforts to reduce flexibility of the medically needy program, to take away our latitude to target disproportionate share in children's hospitals that provide expensive care.

States cannot deficit spend, it has been said. Other proposals would drop the FFP right to 45 percent, that would affect 13 jurisdictions. Very complicated.

In conclusion, let me thank you for the opportunity to be here, to be heard on the plight of the States, and to let you know that we do care. We care very much about the poor. We want to work together in partnership to deal with these issues.

Thank you.

Mr. WAXMAN. Thank you, Mr. Hanley.

[Testimony resumes on p. 145.]

[The prepared statement of Mr. Hanley follows:]

TESTIMONY OF
RAY HANLEY, DIRECTOR
ARKANSAS OFFICE OF MEDICAL SERVICES
and
CHAIRMAN
STATE MEDICAID DIRECTORS' ASSOCIATION
# of the
AMERICAN PUBLIC WELFARE ASSOCIATION

Mr. Chairman, members of the Subcommittee, I am Ray Hanley, Director of the Arkansas Medicaid Program and Chairman of the State Medicaid Directors' Association of the American Public Welfare Association. I appreciate the opportunity to speak with you today on behalf of State Medicaid agencies concerning some of the Medicaid issues and legislation under consideration by members of this Subcommittee, as well as our hopes for broad reform of the health care financing system in this country. I also would like to briefly address our concerns with some of the proposals under consideration in the budget discussion and the potential impact of these proposals on the Medicaid program.

At the outset I must emphasize that state agencies share with Congress a deep concern about the health and welfare of the nation's low-income families. In terms of health care, states have been in the forefront of trying to address the needs of the uninsured and underinsured through innovative programs and strategies which include state-only funds, the Medicaid program, and the involvement of the private sector. Given the rising numbers of uninsured and underinsured Americans, together with the escalating costs of providing health care, states have found it necessary to look to innovation and creative strategies in the absence of any federal reform of the health care financing system. State flexibility has been the key to developing programs that meet both local health policy priorities and local economic conditions.

State Perspective on Medicaid Expansion

State Medicaid programs view new Medicaid expansion options as opportunities for further innovation and experimentation. However, they view expansion mandates with increasing alarm for a variety of reasons, not the least of which is the growing fiscal strain the mandated program expansions place on state budgets. State agencies, however, do not oppose mandates simply because they do not wish to serve the poor.

New studies and analysis repeatedly affirm that state governments have been in the forefront of addressing the needs of low-income and other uninsured populations. States have been developing and enacting programs to address the needs of low-income workers, the high-risk "uninsurables," and populations not eligible for Medicaid. Regarding Medicaid, the majority of states had already elected to cover pregnant women and infants up to the poverty level prior to the mandate to do so. Nineteen states had already moved to cover this population at income levels between 100 and 185 percent of poverty prior to the OBRA '89 mandate for coverage up to 133 percent of poverty. Twenty states already covered older children up to the existing limit of poverty prior to the older children's mandate in OBRA '89. Further, a substantial number of states quickly took up the option to eliminate the assets test for pregnant women and infants.

Developing health policy, setting policy objectives and goals, and implementing programs all require planning. The number of federal mandates handed down to state agencies in the last few years has made planning almost impossible at the state level and the implementation timeframes provided in recent federal statute have compounded this problem. Making substantive changes in short periods of time means that state agencies must put together a program quickly, without benefit of planning or federal agency guidance. Often, a state will get a new program in place only to find that the 'rules' have changed once federal guidance has been issued. This rapid implementation can cause problems in provider relations, client services and state agency morale, all because proper planning cannot occur.

Federal mandates cause other problems at the state planning level which are distinct from timing issues. New programs dedicated to a particular state-determined health policy objective often must be set aside so that funding can be redirected to fulfill the obligations of federal mandates. State agencies do not always concur with Congress that the next federal mandate makes for the best health policy within the state, but state agencies no longer seem to have a choice in policy-setting. Limited resources must be used to meet mandated obligations rather than locally determined policy and program goals.

State Fiscal Concerns

This lack of ability to fund mandates and optional initiatives is due in large part to the fact that growing number of states are having fiscal problems due to changes in the economy. Unlimited growth in the Medicaid program is becoming difficult to sustain. Federal mandates for expansion in the program during times of limited state resources can mean that difficult, but real, choices must be made regarding coverage and eligibility in other parts of the program. It is important to remember that most states are precluded from deficit spending.

A recent report by the National Association of State Budget Officers highlights the increasing pressure on state budgets resulting in large part from increased Medicaid expenditures. In the aggregate, states reported that Medicaid spending is expected to consume 12% of state budgets nationally. Medicaid spending is expected to become the second largest line item in state budgets after primary and secondary education. Program expenditure growth is even more telling. The states reported anticipated spending increases of 18.4% nationally between 1989 and 1990. It appears that fully half the states will have experienced double-digit Medicaid expenditure growth in both the 1988-1989 and 1989-1990 periods. This growth must be viewed with the context of economic downturns anticipated in a growing number of states.

APWA Proposal to Reform the Health Financing System

State agencies believe the time has come to begin a serious dialogue on broad reform of the health care financing system. Although there seems to be a general consensus that Medicaid is an imperfect tool upon which to build a system of universal access, incremental program expansions have been viewed by Congress and others as politically expedient in lieu of any larger consensus on reform. The SMDA believes that mandated Medicaid expansions such as those before the Committee are no longer politically expedient from the state perspective.

The American Public Welfare Association (APWA), representing state human service administrators, has developed a series of policy proposals for reform of the both acute and long term care financing systems. We believe that these proposals represent viable alternatives to the current system and would better assure access and coverage to all those in need. The proposals build on the major components of the current system and embody the concepts of public-private partnership and individual responsibility. The recommendations are similar in their basic concepts to many of the Congressional proposals of the last several years and share several broad characteristics with the recommendations of the Pepper Commission.

On the long term care side, the proposals call for a social insurance model of financing with a focus on the provision of home and community based care. Program eligibility would be based on a level of functional disability, not upon age or diagnosis. Income would not be a criteria for eligibility. The program would provide coverage of institutional services after a waiting period. APWA believes that such a waiting period would encourage the development of private insurance coverage by limiting the underwriter's risk. There would be protection for those with low-incomes who were unable to cover costs during the waiting period. APWA believes that such a program would relieve Medicaid of some of the burden of financing long term care services to a growing number of elderly and disabled people who cannot afford needed care. Long term care services consume roughly 40% of state Medicaid funds nationally, reaching approximately 60% in some states.

Freeing up some of the long term care funds would then allow states to expand access for uninsured and underinsured individuals under the proposal envisioned by state agencies. The APWA proposal calls for expanded employer-based health care coverage. There would be state involvement in facilitating access to affordable policies for small business and government assistance for low-income workers unable to afford the costs of premiums. For the unemployed, uninsured, there would be coverage through a public program providing access to a range of basic preventive, primary and acute care services. While program eligibility would not be means tested, family income would determine the amount of a family's contribution toward the costs of the premium.

These are brief outlines of our proposals and we would be happy to provide more detailed information to you. The important point is that these proposals, developed by human service administrators from across the country, represent a consensus that it is time to move away from a means tested welfare program as the basis of achieving access for a growing number within the population who lack the ability to assure access for themselves and their families.

Options to Improve Medicaid

Until there is comprehensive reform of the health care system, states continue to insist that a variety of well-designed program options will best allow them to address needs at the state and local levels. There is much that should be done to improve the administration of the current program and improve coverage for all those potentially eligible under existing income thresholds.

An option to cover non-medical residential substance abuse treatment services would be welcome by states grappling with how best to provide needed services to pregnant woman. Under current law and regulation, issuance of a Medicaid card to a pregnant woman does not assure all the help needed to facilitate a healthy birth. Simply expanding eligibility under the program will not necessarily help if states cannot find an effective way to help a pregnant woman move away from substance abuse. The increasing numbers of crack addicted babies is testament to the problem.

In terms of eligibility expansions, there are some options that state agencies would like to see enacted in lieu of any mandates. One such option is to provide Medicaid coverage of prenatal care for undocumented pregnant women. Current law allows coverage of emergency services (delivery) but does not permit coverage of prenatal care. Since infants born to these women are citizens that Medicaid is likely to cover, several states are paying through Medicaid the costs of lack of prenatal care for these women. We also believe that a broadly defined option to permit coverage of older children with family incomes of up to 185 percent of federal poverty would allow states to plan for the future while expanding the program. Such a broad option will permit states to rationalize current Medicaid eligibility for younger populations and smooth some of the current jagged Medicaid cliffs. Such an option would facilitate program administration and simplify eligibility.

There are several other changes that are needed in statute to improve or maintain the current program. State agencies would like the option to provide continuous eligibility for infants for a period of up to one year. This would lessen the gaps in coverage that now occur when the mother must reapply for the child after her post-partum period of eligibility ends. This option would facilitate coverage and reduce administrative complexity. State agencies also would like to have the option to drop the assets test for older children. Again, we believe this would facilitate coverage and reduce administrative complexity. Finally, state Medicaid agencies believe that changes in federal presumptive eligibility requirements are necessary to make that program more effective. Legislation before this Subcommittee includes language that would resolve the problem.

We also would urge members of this Subcommittee to protect the current program from erosion due to efforts on the part of the Health Care Financing Administration (HCFA) to eliminate state flexibility with respect to the Medically Needy program eligibility and aged, blind, and disabled eligibility in 209(b) states. Current federal agency efforts to redefine income thresholds and methodology would adversely affect clients across the country. HCFA also is proposing to substantially reduce state latitude to target disproportionate share hospital payments such that states could no longer target high payments to certain types of facilities, such as children's hospitals, which serve a large number of the uninsured. Regulatory change in this area will adversely affect institutions in well over a dozen states. Finally, HCFA is proposing to preclude states from using voluntary contributions and/or provider specific taxes to fund a portion of the Medicaid program. If states are to be able to ensure expansion or even maintenance of the current program, they must be able to decide how the program will be funded.

There are a number of statutory changes that are needed to improve the operation of the current program -- from waiver operation to nursing home reform. We believe there is much that can be done to enhance the program and services for current eligibles.

Concerns Raised by Budget Summit

State agencies remain very concerned about the prospect of reductions in federal financial participation in the Medicaid program through an assortment of proposals apparently under consideration in the budget summit.

Two such proposals, one to reduce the federal matching percentage floor for service from 50% to 45% and the other to eliminate all enhanced administrative matches and then block grant administrative funds, would have significant adverse consequences in states which are already strapped for Medicaid dollars.

The proposal to reduce the floor on federal matching payments for services will have a significant impact in thirteen jurisdictions* where the proposal would shift federal costs for Medicaid and other welfare programs to the states. For the three major programs affected, it has been estimated that $2.1 billion would be shifted to states in 1991, with most of this shift occurring in the Medicaid program.

Proposals to reduce Medicaid administrative funding do not seem to acknowledge the fact that administration of the program has become increasingly complex given new eligibility categories for groups such as Qualified Medicare Beneficiaries (QMBs) and the Qualified Working Disabled. Expansion of the program over the past several years also has led to an increased volume of vendor claims to be processed. In some states the number of claims processed has

* CT, MA, NH, DE, DC, MD, NJ, NY, IL, VA, CA, NE, AK

nearly doubled. There are also complex reforms, such as those for nursing facilities which will require more, not less, administrative resources. Capping administrative funding will harm computer systems innovation. States are looking at changes in claims processing in the hopes of improving provider participation. Systems changes are also required to better monitor delivery of health services to children under the EPSDT program-some of which is now required by federal law.

There are also federal deficit reduction proposals concerning Medicare that would result in increased Medicaid costs. Proposals to increase Medicare Part B premiums will mean direct increases in state Medicaid spending as well since Medicaid pays the premiums for QMBs and other dual eligibles. Similarly, increases in Medicare beneficiary cost sharing obligations and deductibles will mean more state Medicaid spending because of Medicaid coverage of these costs for QMBs.

The point that needs to be emphasized is that many states are having a difficult time sustaining current Medicaid programs; mandates for new spending and cost shifting will force difficult choices in the program such as dropping optional eligibility groups and/or services. States and Congress will likely be dissatisfied with the outcome. For example, in Arkansas, we just eliminated $37 million dollars in anticipated spending by reducing adult dental care services.

We also have had to eliminate adult medically needy coverage. We have been caught in the middle of a biennial budget cycle and the state budget could not afford the new mandates and continued funding of all optional services.

Changes in the Prescription Drug Program

One final issue I would like to address is the discussion of changes in the Medicaid prescription drug program. State Medicaid agencies have been concerned about prescription drug prices for some time. A year and half ago SMDA began discussions on how states could work together, in buying groups, to bring down costs of prescription drug coverage. We continue to explore possible courses of action and have a work group committed to developing proposals.

State agencies are generally supportive of federal efforts to explore this issue. Many states that have tried individually to establish bidding programs have been largely unsuccessful either in obtaining legislative approval or, if they have established programs, in getting manufacturers to bid. Until recently, individual state programs did not carry sufficient leverage to force manufacturers to the table. Since introduction of Senator Pryor's bill in the Spring, the change of heart among manufacturers has been rather rapid. State agencies have been negotiating with several manufacturers on discounts and rebates over the past few months representing significant change in a short time and demonstrating that it is feasible for manufacturers to lower their prices.

With regard to specific drug negotiating proposals under consideration by Congress and the Administration, we would urge caution in several areas. In general, we urge members to be cognizant of the fact that state operations cannot change overnite and that adequate time is needed for substantive changes in program administration. We also encourage Congress to guard against the potential for increased costs associated with either pharmaceutical price increases resulting from any legislation, or inflationary increases on the part of the dispensers of pharmaceutical products. When estimating program savings assumed by the various proposals, Congress should take into account the costs of any computer systems changes required by moving to a national system of drug purchasing. Finally, and most importantly, many state agencies are concerned about the prospect of having to open up their currently closed formularies. This would be an extremely costly proposition for some states, the costs of which are not likely to be offset by rebates or discounts. Such a mandate for an open formulary calls into question one of the basic purposes of these proposals -- to save Medicaid dollars. Again, while access to pharmaceuticals is a clear consideration, the cost of an open formulary on access within the overall program is of at least equal, if not greater, importance.

Conslusion

In conclusion, I would urge Congress to begin serious discussions on the issue of broad health care financing reform. While mandated Medicaid expansions appear politically feasible from the federal level, they are not so feasible at the state level. Medicaid mandates have a very real cost in terms of optional aspects of the program and lost opportunity for state action and innovation not foreseen by Congress. We do believe that there is much to be done in terms of adjustments to current statute to facilitate improved operation of the program, maintaining eligibility for current eligibles and improving coverage for current eligibles. More than ever, state governments need the latitude to establish sound health policy that comports with local needs and conditions. We would urge you to consider these issues as you debate the initiatives and issues before you this year.

I thank you for the opportunity to address these issues of importance to state agencies.

Mr. WAXMAN. Mr. Toews.

STATEMENT OF JAMES D. TOEWS

Mr. TOEWS. Thank you, Mr. Chairman. I am speaking today on behalf of State and Developmental Disability Agencies.

Since the early 1970's, the Medicaid program has played an absolutely crucial role in the expansion and improvement of services to persons with developmental disabilities, and I think H.R. 3934 represents another step, kind of a logical step in looking at how Medicaid should be shaped to serve this particular population.

Current Medicaid policies and practices are badly out of step with contemporary values and practices as they have evolved across the country. For the most part, Medicaid dollars support facility-driven labor intensive clinically based kind of services in congregate care environments.

On the other hand, the field is moving very, very rapidly away from such kinds of models to very locally based creative, innovative kind of services that allow people with disabilities to live longer with their own families and natural homes, to live in small community homes, and to participate in community jobs, and we think it is high time that Medicaid policy catch up with contemporary practices, and that we no longer spend well over 85 percent of the Medicaid dollar in large settings that foster dependency.

We strongly support efforts to fundamentally restructure the whole Medicaid program. The major problems are that current eligibility is tied to an institutional means test and this is almost absurd for the vast numbers of people with disabilities living in the community who have never been in institutions and never will go to institutions. This restricts access to thousands and thousands of people with very severe disabilities who graduate from public schools every year that cannot access the Medicaid dollar.

The ICFMR program which absorbs most of the Medicaid spending now, its costs continue to escalate very, very rapidly, well over double the amount of inflation every year. In many States these costs have doubled, tripled and quadrupled, which is our own case in Oregon over the last 5 years, and that is choking off our abilities to invest dollars for people who have never been in congregate care settings. We lack a permanent mechanism to finance community-based services for people who have not been institutionalized before.

You posed that question to Mr. Jones in terms of the Medicaid waiver, and again the problem with the waiver is that it has an institutional means test which means it is very restrictive and its capacity is capped.

And so in summary, the current Medicaid program simply isn't responsive to changing service transient to the changing nature of the disability population itself.

In terms of looking at the approach of H.R. 3934 for an optional State plan coverage, we think that is a very good approach, but the legislation as it currently is construed poses some problems for us and I want to voice those concerns very quickly.

First of all, I think it imposes a very complex and confusing array of quality assurance requirements spread between the Federal Government and the States that we think will create confusion and a lot of tension, rather than creating a good basis for measuring quality services in the community, plus it adds a lot of the holder nursing home reform into the quality assurance package, and we don't think that represents the best direction of the field.

Part B of the legislation would combine key elements of the ICFMR regulation and the older 1987 nursing home reform provision, and put them in the statute, and quite frankly, we are very concerned about taking regulations for the types of programs that we don't think represent the future of the field, but the past of the field, and enshrining them in Federal statute. We think that is not a good approach.

Another concern that we have is that in this bill the Secretary is given very broad regulatory authority to intrude into the local service policy, including setting minimum personnel qualifications, setting minimum cooperation standards, being able to control the criteria for who gets admitted and discharged and who can stay in ICFMR programs.

I think our example or our experience to date with the waiver program is that when the administration micromanages programs at State and local levels, we have less flexibility and less ability to serve the large numbers of people that are being served, that need the services and the cost tend to escalate.

The maintenance of effort requirement limiting the States' matching share to only newly appropriated dollars, we can understand the logic behind that, but that is a departure from current Medicaid practice and it will discriminate from States that have over the last 5 to 10 years invested an enormous amount of State funds in this program.

It also gives the Secretary somewhat sweeping power to define what State and local expenditures are for purposes of setting the maintenance of effort requirement, and I think that gets into a very complex set of exercises, particularly in determining what local expenditures are for States that operate through country systems and local nonprofit providers, and again I think that degree of micromanagement of the program poses problems.

In summary, we support the general direction of the bill. We think optional plan coverage is very good. We have provided suggestions on how the bill would be improved to the committee and its staff, and we continue to want to work with you on this.

Mr. WAXMAN. Thank you very much.

[The prepared statement of Mr. Toews follows:]

STATEMENT OF JAMES TOEWS ON BEHALF OF THE NATIONAL ASSOCIATION OF STATE MENTAL RETARDATION PROGRAM DIRECTORS

I. INTRODUCTION

My name is James Toews. I am the Assistant Administrator of Developmental Disabilities Services in the Oregon Mental Health and Developmental Disabilities Division. I also serve as Chairman of the Governmental Affairs Committee of the National Association of State Mental Retardation Program Directors. NASMRPD is a non-profit organization of the designated officials in the fifty states and territories who are directly responsible for the provision of long term care services to a total of over half a million children and adults with developmental disabilities.

II. THE NEED TO RESTRUCTURE MEDICAID POLICIES

Over the past two decades, there have been sweeping changes in the provision of publicly-funded services to Americans with developmental disabilities. A wide range of supportive services have been established to promote expanded opportunities for such individuals to live more independent, productive lives in the mainstream of society. Under the leadership of NASMRPD member agencies, large, impersonal public institutions no longer serve as the "hub" of state service delivery systems. While much remains to be accomplished, through the collaboration of state MR/DD agencies, local communities, private providers, and consumer advocacy organizations, tens of thousands of persons with developmental disabilities have been able to claim their rightful place in the community.

The federal-state Medicaid program has played an integral part in these developments, by assuring states access to a reliable source of federal financial aid. The availability of such federal funds has permitted the states to complete long-needed improvements in institutional services, while simultaneously developing diverse arrays of community-based services. Today, one-third of the $13 billion the states spend annually on services to approximately 500,000 individuals with developmental disabilities are derived from federal Medicaid payments and nearly two out of every three dollars expended by the states for this purpose are channelled through the Medicaid program.

Despite the enormous impact Medicaid financing has had on state developmental disabilities programs, it is clear that many of the current statutory and administrative policies that regulate federal payments are poorly synchronized with contemporary values and practices in the field. Existing federal policies fail to affirm the goals of integration and independence or encourage effective methods of service delivery; in addition, they often prevent recipients from engaging in economically productive activities. These policies have their roots in a different era, when "good services" were synonymous with life-long dependency, "comprehensive care" institutions, and protecting people with disabilities from the risks of community life. States have demonstrated, through the provisions of key supportive services in community-based settings, that it is possible to achieve better service outcomes, regardless of the nature and severity of a person's disabilities. It is time, therefore, that federal Medicaid policies affirm this principle as well.

For nearly a decade, NASMRPD and other national organizations have called for a fundamental reformulation of federal policies governing the provision of Medicaid-funded developmental disabilities services. Since 1983, various proposals to change such policies have been debated in Congress, but thus far only relatively minor statutory revisions have been enacted. As we enter the decade of the 90s, the need to reform federal Medicaid policies is, more than ever, a matter of critical nationwide concern. Current policies are out-of-step with the fundamental, overarching values that guide the provision of services to persons with developmental disabilities. Enormous amounts of state and federal Medicaid spending are tied to purchasing services that do not always serve the best interests of the recipients. Unless current policies are substantially altered, the remarkable gains that have been achieved over the past twenty years will be placed in serious jeopardy.

NASMRPD believes it is absolutely essential that immediate attention be given to restructuring the role of the federal Medicaid program in meeting the needs of Americans with developmental disabilities. Among the principal defects in existing Medicaid policies that need to be addressed are:

- ***The inequities associated with existing methods of determining eligibility for Medicaid-funded long term care services, especially the present linkage between eligibility and an individual's presumed need for institutional services.*** In order to qualify a person for Medicaid-financed long term care services under existing federal policies, a state must demonstrate that the individual requires institutional services. Limiting federal assistance to persons who are found to be in need of institutional services works at cross purposes with efforts at the state and local level to foster programs that stress self-sufficiency and full participation in community life. Furthermore, since the number and characteristics of persons receiving institutional care has changed substantially over the past two decades, the institutional needs test has become an increasingly meaningless yardstick for determining any given individual's relative need for ongoing services and supports. As a result, states are left with no ready means of addressing the legitimate service needs of the literally thousands of young adults with severe disabilities who graduate from special education programs each year. While NASMRPD recognizes that there are enormous pressures to reduce the federal budget deficit, it serves no one's interests to deny such individuals vitally needed supportive services designed to enhance their self-sufficiency; the consequences of failing to intervene will be catastrophic, in both human and fiscal terms.

- ***The rapidly escalating cost of delivering ICF/MR services, which is choking off the capacity of states to provide services to unserved persons.*** Escalating federal performance requirements have resulted in a concentration of scarce state and federal resources in ICF/MR-certified facilities. Approximately 85 percent of all Medicaid dollars that are expended on behalf of persons with developmental disabilities are used to support less than 15 percent of the approximately one million individuals, nationwide, who require extended support services as the result of a severe disability originating in childhood. The rising costs of ICF/MR services -- if left unchecked -- threaten to destabilize state developmental disabilities budgets, which inevitably will force the states to restrict access to other needed services.

The lack of a reliable, ongoing mechanism for assuring federal financial participation in the cost of home and community-based services, which avoids the limitations inherent in the existing, Section 1915(c) home and community-based waiver authority. The states have made extensive use of the Section 1915(c) waiver authority to redirect federal Medicaid dollars to supporting a diverse array of community-based services on behalf of persons with developmental disabilities. At present over 40,000 individuals in 41 states are receiving such waiver-financed services. But, the waiver authority has significant limitations as a permanent device for supporting community-based services, both due to the inherent restrictions associated with linking service eligibility to the individual's need for institutional services and the instability of a discretionary waiver authority that gives the Secretary broad administrative powers to impose short-sighted cost containment policies.

The increasing federal intrusion into state administration of service programs, which threatens to undermine the role of the states and local communities in fashioning effective arrays of services for persons with developmental disabilities. Over the past five years, regulation of the ICF/MR program has been increasingly federalized. Furthermore, some federal policymakers and special interest groups have been calling for more stringent federal regulation of community services. In the view of NASMRPD, federal domination of program administration ultimately would undermine the basis of state and local support for community developmental disabilities services. States and communities have played a keystone role in reshaping the provision of such services over the past twenty years. Furthermore, federal rulemaking and oversight will tend to stifle creativity and erode state/local commitments to community services.

The impediments in existing federal Medicaid policies to maintaining a unified, accountable system of delivering developmental disabilities services. Federal Medicaid law often leads to the division of program management responsibilities among several state agencies. As a result, systemwide leadership and accountability become diffused. In an era when resources are scarce, it makes no sense to foster administrative requirements that waste precious dollars on bureaucratic wrangling.

In summary, present federal Medicaid policies pose real obstacles to fashioning state/local service delivery systems that are responsive to the needs of such individuals and promote local "ownership" of programs. If as a nation we are to build on the achievements of the past twenty years, basic federal-state relationships must be reevaluated and current federal policies must be restructured to accentuate constructive approaches which emphasize community-based supports for families and consumers.

III. COMMENTS ON THE "MEDICAID COMMUNITY AND FACILITY HABILITATION SERVICES AMENDMENTS"

Given the Association's longstanding support for legislation to restructure Medicaid policies as they impact on persons with developmental disabilities, NASMRPD members were very encouraged when the distinguished Chairman of the Subcommittee introduced a bill, late in the 100th Congress, to create a new, optional Medicaid state plan coverage of community habilitation services (H.R. 5233). At the time we felt confident that this bill would provide the basic framework for a piece of legislation acceptable to the states as well as to various other groups interested in the welfare of citizens with developmental disabilities.

Unfortunately, the legislation as it eventually emerged from the Subcommittee's budget reconciliation mark up session in June, 1989 (and as subsequently reintroduced as a separate bill (H.R. 3934) this past February) attaches such onerous conditions to the election of the proposed new optional state plan coverage that NASMRPD feels compelled to oppose its enactment. Our principal objections to H.R. 3934 as presently structured can be summarized as follows:

A. Massive Disruption in State Service Delivery Systems. A number of provisions of the bill would require states to abandon long-established precepts that undergird the delivery of community-based developmental disabilities services in order to qualify for coverage of optional community habilitation and supportive (CHS) services under their Medicaid state plans. In particular, H.R. 3934 would:

- ***prohibit a state from abrogating the right of recipients to choose freely among qualified providers of CHS services.*** Under HCFA's interpretation of the statute's existing "freedom of choice" language (Section 1902(a)(23)), states would be prevented from delegating responsibility for overseeing the delivery of services to a single entity within each defined geographic catchment area of the state (e.g., a county or regional agency). Well over half the states currently have such county or regional-based service delivery systems. Such systems would have to be totally revamped under the present terms of the bill.

- ***require a state to provide case management services through an independent entity that is not responsible for furnishing any other elements of CHS services.*** Although last year the Subcommittee narrowed the scope of this problem, at NASMRPD's behest, by limiting the "independence" requirement to non-public entities which are responsible for furnishing CHS-reimbursable services, states which vendorize case management services through a network of designated, regional non-profit agencies (e.g., Colorado and California) still would be required, in all likelihood, to abandon their current approaches, which would result in major disruptions in the delivery of services. Again, there is no empirical evidence that we know of to support the proposition that persons with developmental disabilities are better served as a result of establishing "independent" case management agencies.

- ***imposing a complex, confusing series of community quality assurance requirements which largely ignore the underlying purposes and goals of community developmental disabilities services as they have evolved in recent years.*** Many of the community quality assurance provisions of the bill are modeled after language contained in the 1987 nursing home reform legislation enacted by Congress and, as such, have little relationship to the realities or objectives of overseeing the delivery of community-based DD services. Inherent in many of the bill's requirements is the unstated assumption that services will be facility-based, at a time when a growing number of states are giving priority to the development of non-facility-based services. Compliance with the bill's provisions, therefore, undoubtedly would involve significant increases in service costs without any concommittant assurance of improvements in the quality or accessibility of such services. Indeed, the adoption of such language would have the chilling effect of locking states into service delivery approaches which, increasingly, are viewed as out of step with current thinking in our field.

  Furthermore, the confusing division of responsibility between the federal government and the states in the area of quality assurance would result in intergovernmental conflicts that would impede the effective and efficient delivery of services to eligible recipients. For example, with the exception of state-operated CHS services, the Secretary would be delegated authority to set standards governing the health, safety and welfare of recipients and to assure that such standards are observed, while the states would be obligated to regulate all other aspects of community service delivery. It is not clear how, in practice, the lines would be drawn between health/safety/

welfare issues and other aspects of programming for eligible CHS recipients.

B. Modifications in ICF/MR Requirements. Part B of the legislation would combine key elements of HCFA's revised ICF/MR standards with many of the statutory requirements that were applied to Medicaid-certified nursing facilities under the 1987 reconciliation act (P.L. 100-203). The rationale for such statutory changes are, in our view, highly questionable. To begin with, it is not clear what problem Part B is designed to fix. HCFA has only implemented revised regulations governing the operation of ICF/MRs two years ago. While these rules are not free of controversy, nothing in the pending legislation is intended to rectify perceived problems with HCFA's regulatory and enforcement policies. Instead, the primary aim seems to be to bring ICF/MR policies into closer conformity with the 1987 nursing facility reform legislation (OBRA-87).

There is little evidence to suggest that the applicable OBRA-87 requirements are resulting in demonstrable improvements in Medicaid-certified nursing facilities; indeed, there is a good deal of confusion and disruption stemming from these requirements. Yet, H.R. 3934 would apply the same, untested compliance model to an area of programming for which it was never designed (i.e., ICF/MR).

Of equal importance, the enshrinement of these new requirements in law would exacerbate further the chasm that separates the ICF/MR program from the policies, philosophies and practices that govern all other publicly-supported developmental disabilities services, thus making it even more difficult for the states to pursue a coherent, holistic set of policies aimed at improving and expanding services, systemwide.

The question is not whether ICF/MR residents are entitled to high quality services. Clearly, they are. Rather, the critical issue that must be resolved is: what is the best means of assuring that high quality services are, in fact, delivered. **NASMRPD strenuously disagrees with the assumption that the appropriate means of accomplishing this objective is to embed in the statute an unverified set of federal requirements and subject facilities to an enforcement apparatus that has not been validated.**

C. Broad Regulatory Authority Granted to the Secretary. Throughout H.R. 3934, the Secretary would be empowered to establish key regulatory and administrative policies governing the provision of Medicaid-reimbursable services to persons with mental retardation and related conditions. For example, the Secretary would be directed to issue: (a) standards governing the minimum qualifications of persons providing CHS services; and (b) guidelines setting minimum personnel compensation standards. In other words, the states and local provider agencies would lose control over two critical aspects of program standards: personnel qualifications and compensation. Through an ill-advised attempt to achieve national uniformity on these admittedly critical aspects of program operations, we fear that Congress would stifle state and local innovations, which have been the hallmark of community DD services in recent years.

Furthermore, the states' experiences in operating Medicaid home and community-based waiver programs over the past eight years highlight the dangers of delegating unfettered powers to the Secretary. The history of the waiver program is replete with examples of federal attempts to limit the ways in which a state may use this authority to expand and improve services to low income persons with long term care needs. H.R. 3934 contains numerous provisions which would permit an Administration intent on trimming Medicaid outlays to achieve its purposes. To cite just one example, Part C of the bill would empower the Secretary to establish criteria governing admissions to and continued stays in ICF/MR facilities. In the hands of an unsympathetic Administration, this authority could be used to restrict the types of persons eligible for ICF/MR services, thereby limiting total Medicaid outlays for such services.

This provision is yet another example of a legislative solution in search of a problem. There is no systemic evidence that a significant number of persons who presently reside in ICF/MRs are inappropriately placed. Indeed, the total number of ICF/MR residents has remained relatively constant in recent years and data on the characteristics of the population demonstrate a distinct trend toward serving more severely disabled persons in such facilities.

D. Maintenance of Effort. Section 221(d) of the bill is worded in such a way that it would prohibit a state from using existing state expenditures for community developmental disabilities services to match federal Medicaid dollars available through the new optional CHS plan coverage. In other words, only newly appropriated dollars (i.e., above the level of a state's previous outlays for similar services) could be applied as the state's matching share. Not only would this provision be an unprecedented and dangerous departure from current Medicaid practice, it also would discriminate against states that have made the most significant efforts to develop home and community-based resources for this population through the use of their own fiscal resources.

Furthermore, the language of Section 221(d) would grant the Secretary of Health and Human Services sweeping power to determine the types of state/local expenditures that would be subject to the proposed maintenance of effort requirement. There appears to be nothing which would prevent the Secretary, for example, from demanding that any state/local expenditures remotely connected with community MR/DD services (even states spending for services that would not be Medicaid reimbursable) be declared unavailable for use as CHS matching funds. In the hands of an Administration that is committed to holding down Medicaid outlays, granting the Secretary such unfettered authority would be dangerous. Indeed, should the precedent this provision would establish spread to other parts of the Medicaid program, it could result, eventually, in a backdoor cap on federal Title XIX expenditures -- a result this Subcommittee has long and, thus far, successfully resisted.

E. Employee Protections. NASMRPD agrees that public employees should be protected against the precipitous loss of their jobs or reductions in their job status, pay or benefits when a state decides to close or down-size a publicly-operated MR residential facility. However, the best means of accomplishing this objective is to allow the states broad latitude in designing plans to minimize the negative impacts of a closure or phase-down on affected facility workers (e.g., early retirement; retraining; assistance in locating alternative jobs; preferential hiring rights in other state jobs; etc). It is worth noting that the states, collectively, have closed over 30 publicly-operated MR facilities since 1970 and, with only a few exceptions, have been able to do so without laying off workers who wished to remain in state service.

However the so-called Madigan Amendment, which was adopted during the Subcommittee's 1989 mark-up of the legislation, would force a state to offer any worker displaced by the closure or phase-down of a state MR facility the opportunity to be employed **in a CHS-supported facility or program.** The effect of this unprecedented intrusion into the states' management prerogatives would be particularly severe in states which do not directly operate community DD services (i.e., the large majority of states). Enormous morale problems would result if the state were to attempt to force private provider agencies to hire former state employees at salary and benefit levels far in excess of the existing standards for community workers. While increasing the wages of the existing community work force to a level comparable to state employees performing similar work would be desirable, the additional dollars that would be required to do so would result in sharply increased federal-state Medicaid costs. Such increases no doubt would make it even more difficult for the states to expand services to needy persons who, in many jurisdictions, already have to wait for months or even years to be admitted to an appropriate facility or program.

IV. CONCLUSION

NASMRPD is committed to improving community-based and institutional services for persons with mental retardation and related conditions. We know and appreciate the fact that the Subcommittee seeks the same goal. However, as an organization representing the principal state officials who would be responsible for implementing H.R. 3934, we feel obligated to inform you that the bill, in its present form, would do more harm than good. Given the effects of the "maintenance of effort" language and the various ways in which states would be required to compromise basic tenets of their existing community DD service systems in order to qualify for federal assistance, we sincerely believe that few, if any, states would be likely to adopt the proposed new state plan coverage.

In addition, whether or not they elected to adopt the proposed new state plan option, states would be forced, for no clear purpose, to cope with the inevitable disruptions that would accompany a whole new set of operating requirements governing ICF/MR facilities, a scant two years after the implementation of new federal ICF/MR standards.

None of the defects in H.R. 3934 are, in our opinion, irreconcilable. However, they would involve a basic reassessment of the goals of the legislation and the best methods of achieving them. In some instances, relatively minor modifications would solve the problems we have identified; in others, more far-reaching changes would be necessary. In any event, I want to assure you that our Association remains ready to assist Subcommittee members and staff in finding appropriate means of addressing these problems. Indeed, we already have shared with the Subcommittee's staff an extensive list of suggestions for improving the bill.

* * * * * *

On behalf of the Association, I want to express to the Subcommittee my appreciation for this opportunity to offer our organization's views concerning the important legislation you are now considering. If we can be of further assistance to the Subcommittee when this legislation is marked up, I hope you will call on us.

Mr. WAXMAN. I want to thank each of you for your presentation today. I have no questions, but I do have a comment.

Today is September 10, 1990. Just 4 days ago, Secretary Sullivan released "Healthy People 2000," which outlines health goals for the Nation within the next 10 years.

I want to quote from Dr. Sullivan's remarks. "We must find ways to extend the benefits of good health to those who are the most vulnerable among us. Most of the vulnerable lack financial resources, very low educational attainment, are either unemployed or work in low-paying jobs and suffer social disadvantages. Many are children, some are older adults. Far too many belong to racial and ethnic minorities."

Well, this subcommittee thinks it has found a way to use Dr. Sullivan's phrase "to extend the benefits of good health to those who are the most vulnerable among us." That way is incremental expansion of Medicaid, the program that pays for health care for the poor.

That is why the House budget resolution sets aside resources for the Collins-Hyde, Hyde and Slattery-Waxman bills, among others. Yet we are sitting here this morning debating whether by July 1, 1993, 3 years from now, all States and the Federal Government will have to extend Medicaid coverage to pregnant women and infants with incomes below 185 percent of the poverty level, so that these high-risk women will have access to prenatal care. That will be 5 years after Mr. Bush made the promise that he would enact such legislation.

We are sitting here this morning debating whether by October 1 of the year 2000, 10 years from now, all States and the Federal Government will have to extend Medicaid coverage to all poor children under the age of 18, so that those children will have access to the preventive and primary care services they need to develop into healthy, productive citizens. That is 12 years after Mr. Bush made the proposals to do exactly this.

In your statement, Ms. Taylor-Little, you found it incredible that Congress would want the States to implement nursing home reform on October 1, 3 years after the law was enacted.

Well, we find it incredible that the States can't distinguish between reasonable and unreasonable requirements. To me, the Collins-Hyde bill and the Slattery-Waxman bills are a modest but critical long-term investment in our Nation's future. I believe both the Federal Government and the States have an obligation to invest the resources necessary to reduce infant mortality and improve the health of our children.

I regret that some members of this panel don't share that perspective. I appreciate what you have said. We will look forward to working together, and we know we would like to see the same goals. The question is whether we are going to do it, and how we are going to do it, how long it is going to take to get there.

We are going to recess now until 2 o'clock and we will reconvene in this room.

Thank you very much.

[Whereupon, at 12:10 p.m., the subcommittee recessed, to reconvene at 2 p.m., this same day.]

AFTER RECESS

Mr. **Waxman**. The meeting of the subcommittee will come back to order.

Our final witness today is Dr. Gail Wilensky.

Since February of this year, she has served as the Administrator of the Health Care Financing Administration, where she is responsible for the management of both the Medicare and the Medicaid programs. If it is possible to be over qualified for a position that involves managing two health care programs that will spend over $150 billion this year, Dr. Wilensky is.

An economist by training, she is a nationally recognized expert on health policy. She has an extensive experience in the private sector and academia and in the Federal Government where she directed the analysis of the national Medicare expenditure survey.

Before appointment as HCFA administrator, she served on the Physicians' Payment Review Commission. One of the many remarkable things about Dr. Wilensky is that she came to HCFA with a working knowledge of the Medicaid program, an understanding of its rule in our Nation's health care financing system and the commitment to reform.

She has already set a record for the quickest bureaucratic reorganization by establishing within HCFA a new Medicaid bureau and she is trying to reduce the long delays in developing and initiating to implement congressional initiatives.

Welcome to the subcommittee. I am sure I speak for the other members as well when I tell you that we look forward to working with you and your new bureau to improve the program to meet the health care needs of America's poor.

Without objection, your statement is going to be inserted in the record in full.

What we would like to ask you to do is to proceed with your oral presentation and be prepared to answer some questions afterwards.

STATEMENT OF GAIL R. WILENSKY, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Ms. **Wilensky**. Thank you very much, Mr. Chairman, and members of the subcommittee.

I am pleased to be here this afternoon to discuss Medicaid in its 25th anniversary year.

Medicaid is our Nation's largest source of health care financing for low income individuals. In the past 25 years, Medicaid has helped tens of millions of Americans, and I believe we can make it even more responsive and responsible in the future.

When I began my tenure as administrator, I committed to the establishment of a Medicaid bureau to send an important signal. It gives emphasis to the program which serves our neediest population. This Medicaid bureau will also enable us to effectively address the policy and operational concerns addressed by the States.

I recognize that the Medicaid program is confronted with serious issues that do not lend themselves to easy solutions. While Medicaid is able to reach millions of Americans, many others lack adequate health care access. This creates severe tension at a time of fiscal austerity. It forces us to work hard to find innovative approaches to provide service within fiscal constraints.

Under the President's budget, Federal Medicaid expenditures in fiscal year 1991 would increase by $6.7 billion to $47.6 billion, a 16 percent increase over fiscal year 1990. The fiscal year 1991 budget includes $300 million in the base line for expanded Medicaid coverage to larger numbers of pregnant women and children. Medicaid is expected to serve more than 26 million recipients in fiscal year 1991, an increase of almost 5½ percent over fiscal year 1990.

In the past several years, Congress has enacted expansions which will have an impact on the Federal-State spending in fiscal year 1991. These expansions have increased the number of pregnant women, infants and children receiving services. It has required States to pay Medicare premiums and copayments for poor, elderly and disabled Medicaid recipients. It has increased coverage of the working poor. It has provided protection from spousal impoverishment and required quality reform in nursing homes.

States will feel new fiscal pressures from this over the next few years. Of the total expected increase in fiscal year 1991 Medicaid spending, these and other expansions are responsible for about 18 percent, $1.2 billion.

To pay for their share of Medicaid costs, States may find themselves forced to contend with the hard choice of cutting resources from other programs such as education and transportation, or to raise more revenues.

As you know, in July 1989, the National Governors Association asked the administration for a 2 year moratorium on further mandates for Medicaid expansion. The Administration believes that the acute financial situation of the States and the consequences for other important public proposals posed by the rapid growth in Medicaid add to the argument that now is not the time to require States to devote more resources to Medicaid.

In general, I know that many of you are frustrated by the constraints we face while we consider further program expansions as remedies for problems that we all can agree are real and need attention. I feel this frustration myself.

Federal resources have always been limited, but this is now being compounded by the persistent Federal deficit. Escalating health care costs play a significant part in our current budget crises. Between 1980 and 1990, costs for the Medicare and Medicaid programs have more than tripled, while the GNP has doubled.

While I am not suggesting that we should have or could have held health care costs per capita to the same rate of increase as the per capita GNP, had we done so, the deficit would be $39 billion less. With that perspective, it is clear that we must devote serious attention to innovative approaches to health care that could moderate the inflationary incentives of our fee-for-service care.

If we cannot get cost escalation under control, we will fight a losing battle on improving services. Approaches such as payment reform, managed care systems, selective contracting, and competitive bidding to promote positive financial incentives for better value for health care meet resistance. I find that as frustrating as I find the limits the budget process place on all of us.

Let me describe a few ideas that I believe could serve as a start.

Managed or coordinated care represents one of the most important health care strategies for maintaining standards of excellence, while at the same time holding great promise for improving the effectiveness and efficiency of our health care system within the constraints of a tight Federal budget.

The administration is committed to prepaid managed health care. HMO's and similar managed health care plans have demonstrated their ability to provide high quality health care at an affordable price.

While it would not be appropriate in light of the budget situation to request added funds for this initiative, we will continue to emphasize managed care.

Within the Medicaid Bureau, I have established an Office of Managed Care to promote the administration's goal of increasing the enrollment of Medicaid recipients in managed care plans.

Currently, only about 5 percent of Medicaid recipients are enrolled in capitated managed care plans. This number has remained fairly constant over time.

We have developed a number of legislative proposals which would encourage more managed care plans to accept Medicaid enrollees. These are explained in my written statement for the record.

While increasing the flexibility of States to implement managed care programs, we would expect them to have adequate outcome-oriented quality assurance systems. As soon as the details of our Medicaid proposal have been developed to our satisfaction, we will have a Medicaid managed care package. We hope that the committee will lend its support to this proposal.

We are moving without delay to make program improvements that should help Medicaid be more responsive to recipients. I would like to mention some of the steps that HCFA is taking to improve the administration and operation of the existing program.

We are improving the home and community-based service waiver process. The States have used waivers to find innovative ways to meet the health care needs of Medicaid recipients, and to move away from costly institutional services to community-based care.

We will improve and expedite the home and community-based waiver process. I believe we can reduce documentation requirements without compromising principles of cost-neutrality or quality of care.

We are engaging in revisions in the regulations process. I am committed to improve the timeliness and quality of the development and clearance of HCFA regulations. I appointed a regulations review task force which has made recommendations that will lead toward attainment of this goal.

Now that our revised procedures are in place, the time needed to process a regulation will be decreased, I hope from 130 working days to less than 90 days.

We are also implementing expansions and reforms. About 37 percent of all of our Medicaid expenditures go to long-term nursing home care. As we move forward to implement comprehensive reform of Federal regulation of nursing homes, the quality of care and the quality of life should continue to improve for the residents in America's nursing homes.

Successful pregnancy outcomes and healthy children are the building blocks of our Nation's future. States are now required to cover pregnant women and children up to age 6 with family incomes below 133 percent of the Federal poverty level.

While expanded Medicaid eligibility for pregnant women and children will help to improve the health of our Nation's children, we are deeply concerned about another problem—the growing number of substance abusing pregnant women and their infants who are born drug and alcohol exposed.

The Medicaid Bureau recently sent a letter to each State director summarizing services that are available through Medicaid for substance abuse treatment. Also, HCFA plans to fund projects in three to five States to demonstrate substance abuse treatment programs that are not currently offered under their State plans.

Coordination of Medicaid services with other programs for the same target groups will maximize the availability of services.

With the Maternal and Child Health Bureau, we are encouraging outreach to enroll eligible individuals and to improve prenatal care.

As the administration and Congress consider changes in Medicaid, we must consider that health care has become increasingly expensive. Many of the reasons for this are beyond our control, and reflect many forces, including a societal demand that at times seem unlimited. Even so, we must be careful that legislation does not exacerbate cost escalation.

I know you are interested in our position on the Medicaid bills pending before this subcommittee. If enacted, these proposals would substantially increase Medicaid spending. We estimate that the six key bills would cost $350 million in fiscal year 1991 and more than $11 billion over the next 5 years.

In light of the Federal budget implications and our concern for State budgets, at this time we cannot support these proposals.

We also have specific concerns about some of the bills. We believe it is commendable to decrease emphasis on institutional care in favor of home and community-based services. The two community care bills before the committee would alter the scope of the Medicaid program by adding many nonmedical social services to the list of optional services already available. These bills will noticeably increase Medicaid spending in excess of $5.5 billion over the next 5 years.

We are also examining the appropriateness of a mechanism for assuring the quality of services provided in home and community settings. Many of the home and community-based services proposed for reimbursement by these bills can already be provided by Medicaid as optional services or under waivers.

As I stated earlier, I am interested in improving the process by which States seek and are granted waivers in an effort to increase utilization of such options as alternatives to institutional care.

It is anticipated that the Medicaid program will spend $870 million under the current program for HIV diseases in fiscal year 1991. The bill that is under consideration would add to optional Medicaid eligibility a new group of individuals who have tested positive for HIV, but who do not necessarily display symptoms of AIDS or opportunistic diseases.

We believe it is inappropriate to establish Medicaid eligibility on the basis of a specific disease. We estimate that this bill would increase costs to the Medicaid program by $270 million in fiscal year 1991, and to cost about $2.9 billion over 5 years.

There are several trends having a profound effect on our Nation's health care system. The aging of our population, changes in morbidity and mortality, and the increased use of technological advances in medicine lead to changing needs of people served by the Medicaid program. These factors have contributed to issues facing our health care system.

You may know that I am serving as vice-chair of a task force appointed by Secretary Sullivan to study what I have already identified as our most compelling problem—access to basic health insurance for those who lack it.

Let me reaffirm the administration's commitment to those who need help in obtaining basic health insurance. At the same time, I acknowledge that these are challenging times with difficult decisions that must be made. As we consider these tough decisions, I sound this note of caution: Potential solutions must consider the financial consequences over both the short and long term.

Mr. Chairman, we share a commitment to quality health care for the poor. I hope we can share our skill in finding the best way to assure it.

Thank you for the opportunity to appear before you at this hearing, and I will be pleased to answer any questions you may have.

[Testimony resumes on p. 186.]

[The prepared statement and attachments of Ms. Wilenksy follow:]

STATEMENT OF
GAIL R. WILENSKY, PH.D.
ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairman and Members of the Committee:

I am pleased to be here this morning to discuss Medicaid. In its 25th anniversary year, Medicaid is our nation's largest source of health care financing for low-income individuals. In 1989, the Medicaid program paid for services provided to 23.5 million low income persons who were in families with children or who were pregnant, aged, disabled or blind. From $734 million dollars in 1966, the Federal investment in Medicaid has grown substantially, and is expected to exceed $40 billion in 1990. States will commit an additional $31 billion of their own funds in 1990 as their share of the State-Federal partnership. In the past twenty five years Medicaid has helped tens of millions of Americans and I believe we can make it even more responsive and responsible in the future.

MEDICAID BUREAU

When I began my tenure as Administrator, I committed to the establishment of a Medicaid Bureau. In just three months the Bureau became a reality, and I am happy to report that by mid-September, Christine Nye, Director of the Wisconsin Medicaid Program, will become Director of HCFA's new Medicaid Bureau.

First, the creation of the Medicaid Bureau sends an important signal: It gives emphasis to the program which serves our neediest population -- those with income and resources inadequate to obtain basic health care protections.

The Medicaid Bureau also will enable us to effectively address the policy and operational concerns expressed by the States. We want to both improve management of the Medicaid program and ensure that States retain needed flexibility in determining the nature and scope of their own programs. To accomplish all of this will require greater cooperation between the States and HCFA. It is through a partnership between the States and the Federal government that Medicaid serves close to 25 million Americans. That partnership needs to function as well as possible.

UNINSURED/PRESSURE ON BUDGET

I recognize that the Medicaid program is confronted with serious issues that do not lend themselves to easy solutions.

While Medicaid is able to reach millions of Americans, many others lack adequate health care access. This creates severe tension at a time of fiscal scarcity. It forces us to work hard to find innovative approaches to providing service within fiscal constraints.

Under the President's budget, Federal Medicaid expenditures in FY 1991 would increase by $6.7 billion to $47.6 billion, a

16 percent increase over FY 1990. (We expect 1990 expenditures to increase by 18 percent over 1989.) The FY 1991 budget includes $300 million in the baseline for expanded Medicaid coverage to larger numbers of pregnant women and children. Medicaid is expected to serve more than 26 million recipients in FY 1991, an increase of almost 5.5 percent over FY 1990.

Budget constraints may cause many States to limit the number of optional benefits they cover, even though the Federal government will pay from 50 to 83 percent of expenses. Medicaid program expenditures are expected to increase at an average rate of about 12 percent each year for the next five years. States tell us that Medicaid now accounts for about 11 percent of their budgets, (projected to increase to 12 percent in 1992). Many States view the Medicaid program as their primary competitor for scarce funds. This is not surprising. Since the Medicaid program's inception, rapidly rising health care costs have grown faster than State revenues.

In the past several years Congress has enacted expansions which will have a major impact on State-Federal spending in fiscal year 1991. These expansions have increased the number of pregnant women, infants, and children receiving services; required States to pay Medicare premiums and co-payments for poor, elderly and disabled Medicaid recipients; increased coverage of the working poor; provided protection from spousal impoverishment; and required quality reform in nursing homes.

Many of these expansions are effective October 1st of this year; however, others have delayed or staggered effective dates, and States will feel new fiscal pressure from this over the next two years.

Of the total $6.7 billion expected increase in FY 1991 Federal Medicaid spending, these and other expansions are responsible for about 18 percent -- $ 1.2 billion. To pay for their share of Medicaid costs, States may be forced to contend with the hard choice of cutting resources from other programs such as education and transportation, or raising more revenues.

As you know, in July, 1989 the National Governors' Association asked the Administration for a two-year moratorium on further mandates for Medicaid expansions. The Adminstration believes that the acute financial situation of the States, and the consequences for other important public proposals posed by the rapid growth in Medicaid, add to the argument that now is not the time to require States to devote more resources to Medicaid.

You have pending before the Subcommittee proposals that would further expand the Medicaid program. I will address these specific proposals later in my statement.

In general, I know that many of you are frustrated by what may be perceived as the Administration's unwillingness to consider further program expansions as remedies for problems that we all can agree are real and need attention. I feel this frustration myself. Federal resources have always been limited, but this is compounded by the persistent Federal deficit which makes it even more difficult to deal with problems such as access to health care.

Escalating health care costs play a significant part in our current budget crisis. Between 1980 and 1990 costs for the Medicare and Medicaid programs have more than tripled, while the GNP has doubled. While I am not suggesting that we should have, or could have, held health care costs per capita to the same rate of increase in the per capita GNP, had we done so, the deficit would be $39 billion less.

With that perspective, it is clear that we must devote serious attention to innovative approaches to health care that could moderate the inflationary incentives of fee-for-service care. If we cannot get cost escalation under control, we will fight a losing battle on improving services.

Approaches such as payment reform, managed care systems, selective contracting and competitive bidding to promote positive financial incentives for better value for health care meet resistance. I find that as frustrating as I find the limits the budget process places on all of us.

Let me describe a few ideas that I believe could serve as a start.

Managed, or "coordinated" care, represents one of the most important health care strategies for maintaining standards of excellence, while at the same time holding great promise for improving the effectiveness and efficiency of our health care system within the constraints of a tight Federal budget.

Coordinated care systems which encompass a wide variety of delivery arrangements, such as health maintenance organizations and primary care case management organizations, can offer many advantages for Medicaid recipients. Coordination of their care can mean increased access for recipients to a more extensive range of services than traditional fee-for-service arrangements can offer. Coordinated care can ensure access to primary care, continuity of care, and coordination of specialist and inpatient services. Also, Coordinated care systems operate in an environment that promotes the efficient management of health care resources.

The Administration is committed to prepaid, managed health care. HMO's and similar managed care plans have demonstrated their ability to provide high quality health care at an affordable price. While it would not be appropriate, in light of the budget situation, to request added funds for this initiative, we will continue to emphasize managed care.

Within the Medicaid Bureau I have established an Office of Managed Care to promote the Administration's goal of increasing the enrollment of Medicaid recipients in managed care plans. Currently, only about 5 percent of Medicaid recipients (1.3 million) are enrolled in capitated managed care plans. This number has remained fairly constant over time.

We have developed a number of legislative proposals which would encourage more managed care plans to accept Medicaid enrollees. These changes are essential if we are to increase Medicaid enrollment in manged care plans. Our proposals would:

- Permit States to implement a mandatory managed care system using the State plan option instead of waivers.
- Allow the States to guarantee to any HMO with a Medicaid contract and to other primary care case management providers, the six-month minimum enrollment period, and one-month extension of eligibility to enrollees when Medicaid

eligibility is lost, usually for administrative reasons.

- Give public HMOs a new basis for obtaining a waiver of the 75 percent limitation on Medicare and Medicaid enrollment by allowing them to demonstrate that they have exhausted good faith efforts to enroll non-Medicaid or Medicare persons.
- Permit waivers of enrollment composition requirements for an indefinite period of time for any HMOs in medically underserved areas.
- Allow States to permit any Medicaid HMO which meets the enrollment composition requirements to restrict Medicaid enrollees from voluntarily disenrolling from an HMO without cause for at most six months and not during the first month.
- Permit States to make payments on a prepaid capitation basis to HMOs participating in Medicare but not Medicaid for services provided to dual eligibles.
- Allow States to require eligible individuals to elect, at the time they apply for Medicaid benefits, either to enroll in an HMO or other available managed care program, or to obtain care on a fee-for-service basis. States choosing this option could also elect to enroll automatically, in a managed care plan, any applicant who failed to make a choice. Medicaid eligible individuals would be entitled to terminate such enrollment without cause after one month, to appeal an automatic enrollment on grounds of undue hardship, and to be notified of their rights to these remedies.

While increasing the flexibility of States to implement managed care programs, we would expect them to have adequate outcome-oriented quality assurance systems.

As soon as the details of the quality assurance component of our proposal have been developed to our satisfaction we will have a Medicaid managed care package. We hope that the Committee will lend its support to this proposal.

The primary program management proposal in the President's budget is one that would consolidate all Medicare and Medicaid State certification activities in a new Survey and Certification Revolving Fund, and make this account self-sustaining through the assessment and collection of user fees. This proposal is a logical extension of the laboratory inspection funding mechanism mandated by the Congress in the Clinical Laboratory Improvement Amendments of 1988. It is an effort to equitably assign costs to those parties who most benefit from participation in the Medicare and Medicaid programs.

HCFA INITIATIVES

We are moving without delay to make program improvements that should help Medicaid be more responsive to recipients. I would like to mention some of the steps HCFA is taking to improve the administration and operation of the existing program.

Improvement in the home and community-based services waiver process --- The States have used waivers to find innovative ways to meet the health care needs of Medicaid recipients, and to move away from costly institutional services to community-based care. We will improve and expedite the home and community-based services waiver process. I believe we can reduce documentation requirements without compromising principles of cost-neutrality or quality of care.

Revisions in the regulations process --- I am committed to the improvement of the rulemaking process within HCFA. Recognizing past problems, my goal is to improve the timeliness and quality of the development and clearance of HCFA regulations. I appointed a Regulations Review Task Force which has made recommendations that will lead toward attainment of this goal. Now that our revised procedures are in place, the time needed to process a regulation will be decreased -- I hope from 130 to less than 90 days. The Medicaid program is extremely complex and I believe it is incumbent upon HCFA to provide States with necessary regulatory guidance in a timely and efficient manner.

Implementation of Existing Expansions/Reforms

About 37 percent of all Medicaid expenditures go for long term nursing home services. As we move forward to implement comprehensive reform of Federal regulation of nursing homes, the

quality of care and quality of life will continue to improve for the residents in America's nursing homes.
Successful pregnancy outcomes and healthy children are the building blocks of our nation's future. States are now required to cover pregnant women and children up to age six with family incomes below 133 percent of the Federal poverty level.

While expanded Medicaid eligibility for pregnant women and children will help to improve the health of our nation's children, we are deeply concerned about another problem - the growing number of substance-abusing pregnant women and their infants who are born drug and alcohol-exposed. The Medicaid Bureau recently sent a letter to each State Director summarizing services that are available through Medicaid for substance abuse treatment. Also, HCFA plans to fund projects in 3-5 States to demonstrate substance abuse treatment services not currently offered under their State plans.

The ADAMHA basic block grant to States provides additional support for substance abuse treatment and prevention for pregnant women and for women with dependent children. To improve drug treatment efforts supported through the block grant, the Department has submitted a proposal that would require the approval of State drug treatment plans as a condition for receiving block grant funds.

Coordination of Medicaid services with other programs for the same target groups will maximize the availability of services. With the Maternal and Child Health Bureau, we are encouraging outreach to enroll eligible individuals and improve prenatal care.

HCFA and PHS have executed a memorandum of understanding with the American College of Obstetricians to assist HCFA and State Medicaid agencies in improving the recruitment and retention of obstetrical providers. The agreement calls for the development of an effective practices guide on recruitment and retention and a guide for OB participation in Medicaid's maternal and infant health initiative.

Implementation of the OBRA 89 EPSDT provision is also an important agency priority. Prior to the July issuance of HCFA Manual Instructions, I met on several occasions with both the Children's Defense Fund and the American Academy of Pediatrics to assure that necessary input from these organizations was considered.

LEGISLATION PENDING BEFORE THIS COMMITTEE

As the Administration and Congress consider changes in Medicaid. we must consider that health care has become increasingly expensive. Many of the reasons for this are beyond our control and reflect many forces, including a social demand that at times seems unlimited. Even so, we must be careful that legislation does not exacerbate cost escalation.

I know you are interested in our position on the Medicaid bills pending before this subcommittee. If enacted, these proposals would substantially increase Medicaid spending. We estimate that the six key bills (H.R.s 3931 through 35 and H.R. 4080) would cost $350 million in FY 1991 and more than $11 billion over the next 5 years. In light of the Federal budget implications and our concern for State budgets, we cannot support these proposals at this time.

We also have specific concerns about some of these bills:

H.R. 3933 (The Medicaid Frail Elderly Community Care Amendments of 1990) and H.R. 3934 (The Medicaid Community and Facility Habilitation Services Amendments of 1990.

We believe it is commendable to decrease emphasis on institutional care in favor of home and community-based services for highly vulnerable groups -- persons with mental retardation and other developmental disabilities and the frail elderly. However, these two pending bills will noticeably increase Medicaid spending -- in excess of $5.5 billion over the next five years by our estimate. These proposals would alter the scope of the Medicaid program by adding many non-medical social services to the list of optional services already available.

We are also concerned about the appropriate mechanism for assuring the quality of services provided in home or community settings. The 1987 nursing home reform provisions prescribe a set of standards for care which can be monitored and enforced by Federal and state surveys. This becomes an even more difficult task when considered in light of the many diverse settings for care which would be possible under these proposals.

Many of the home and community-based services proposed for reimbursement by these bills can already be provided by Medicaid as optional services or under waivers. As I stated earlier, I am improving the process by which States seek and are granted waivers in an effort to increase utilization of such options as alternatives to institutional care.

H.R. 4080 (The Medicaid AIDS and HIV Amendments of 1990.)

It is anticipated that the Medicaid program will spend $870 million under the current program for HIV diseases in FY 1991. This bill would add to optional Medicaid eligibility a new group of individuals who have tested positive for HIV but who do not necessarily display symptoms of AIDS or opportunistic diseases. We believe it is inappropriate to establish Medicaid eligibility on the basis of a specific disease. We estimate this bill to increase costs to the Medicaid program by $270 million in FY 1991 and to cost about $2.9 billion over five years.

CONCLUSION

There are several trends having a profound effect on our nation's health care system. The aging of our population, changes in morbidity and mortality, and the increased use of technological advances in medicine lead to changing needs of people served by the Medicaid program.

These factors have contributed to issues facing our health care system. The diversity of opinion as to what the unmet needs are, how to remedy deficiencies, and how to finance further program expansions are evidenced by the number of task forces and commissions which have been established to address these problems and recommend solutions. You may know that I am serving as Vice-chair of a task force appointed by Secretary Sullivan to study what I have already identified as our most compelling problem -- access to basic health insurance for those who lack it.

Let me re-affirm the Administration's commitment to those who need help in obtaining basic health insurance. At the same time I acknowledge that these are challenging times, with difficult decisions that _must_ be made. As we consider these tough decisions I sound this note of caution. Any changes in our health care system must be made in a way that does not lead to further cost escalation and overwhelming financial gaps in the future. We must make sure that we do not create incentives that lead to unnecessary utilization and overspending in the future. Potential solutions _must_ consider the financial consequences, over both the short and long term.

Mr. Chairman, we share a commitment to quality health care for the poor. I hope we can share our skill in finding the best way to assure it.

Thank you for the opportunity to appear at this hearing. I will be pleased to answer any questions you may have.

States which have had State Medicaid plan amendments approved by HCFA as of August 15, 1990

1.) Payments for Nursing Facility Services. Section 4211(b) (2) of the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203) requires each State to submit, no later than April 1, 1990, a State plan amendment that provides for an appropriate adjustment in payment amounts for nursing facility services which takes into account the costs of complying with the requirements of nursing home reform, effective October 1, 1990.

> HCFA developed a detailed manual instruction that clearly indicated that States were required to develop detailed estimates of the costs of the new requirements. Our instructions were widely circulated for comment to both States and LTC providers before it was finalized. The approval process is complicated and involves a great deal of consultation and review by HCFA, both at the central and regional office level. As of August 15, 1990 only one State (Washington) had its State plan amendment approved by HCFA. We had received 35 State plan amendments on or before April 1, 1990. Overall, 49 State plan amendments have been submitted, two States have either submitted a draft document or withdrawn their plan amendment. Five amendments submitted recently are under initial review. We have asked for additional information on 44 the plan amendments submitted and have received follow-up replies from 41 States. As of September 8, 1990, we have 19 additional State plan amendments that are approvable and more are expected to be approved soon.

2.) Payments to Disproportionate Share Hospitals. Section 1923(a)(1)(B) of the Social Security Act requires each State to submit, no later than April 1, 1990, a State plan amendment that defines disproportionate share hospitals and provides, effective July 1, 1990, for an increase in the rate or amount of payment to such hospitals for inpatient services consistent with the requirements of section 1923(c).

> To date, 46 States have approved State plan amendments for payment to disproportionate hospitals under Medicaid (see attached list). Three States have submitted State plan amendments that are pending approval. One State (Maryland) has not yet submitted a plan amendment and we are working with them through our Regional staff to resolve the issues.

3.) Medicaid Transitional Coverage for Working Welfare Families. Section 303 of the Family Support Act of 1988, P.L. 100-485, requires each State to extend Medicaid coverage for 12 months to individuals who lose cash assistance under the AFDC program due to earnings and who, during the 12 month period, continue to report earnings. This requirement is effective April 1, 1990.

> As of August 15, 1990, 31 States had their State plan amendments approved for Medicaid transitional coverage under the Family Support Act.

4.) Payments for Obstetrical and Pediatric Services. Section 1926 of the Social Security Act requires each State to submit, no later than April 1, 1990, a State plan amendment that specifies the payment rates to be used for obstetrical and pediatric services delivered on or after July 1, 1990. These rates must be sufficient to enlist enough providers so that care and services are available to Medicaid beneficiaries at least to the extent that they are available to the general population in the geographic area.

> As of August 15, 1990, 23 States had their State plan amendments approved for payment for obstetrical and pediatric services, 4 States have their plan amendments under review, 21 States have had their plan amendments disapproved, and 2 States (California and Colorado) have not yet submitted a plan amendment.
>
> For the disapprovals, HCFA has determined, based on the data that the States have submitted, that the States do not comply with the statutory requirements of section 1926 and 1902(a)(30)(A) of the Social Security Act. In general, these States have been unable to document that their payment rates for obstetric and pediatric services were sufficient to enroll enough providers into their Medicaid programs so that care and services are available under Medicaid at least to the extent that services are available to the general population in the geographic area. In some cases, States submitted only partial payment rates and no other data. In others, data submitted were irrelevant and unrelated to the statutory requirements. We are continuing to work with the States to facilitate the review process.

5.) Early and Periodic Screening, Diagnosis, and Treatment Services. Section 6403 of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, expands the EPSDT benefit for children to include services necessary to correct or ameliorate problems discovered through screening, whether or not those services are covered under the State's Medicaid plan. This requirement is effective April 1, 1990.

> The EPSDT requirements under OBRA-89 did not specifically

require State plan amendments be filed. However, 18 States have submitted State plan amendments for EPSDT. No State plan amendments have been disapproved.

6.) Payments for Federally-Qualified Health Center Services. Section 6404 of the Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, requires each State, effective April 1, 1990, to extend Medicaid coverage for Federally-qualified health center services and any other ambulatory services offered by Federally-qualified health center which are otherwise included in the State's Medicaid program. The centers are to be reimbursed 100 percent of the reasonable costs of delivering services.

As of August 15, 1990, 13 States had their State plan amendments approved. We are working to help facilitate the approval process for the remaining States. In addition, we are working closely with PHS to refine their criteria to identify centers that could qualify as federally-qualified health centers.

Approved State Plan Amendments as of August 15, 1990

PAYMENTS FOR NURSING FACILITY SERVICES - 1 State
(Section 4211(b)(2) of OBRA 87, P.L. 100-203)

Washington

MEDICAID TRANSITIONAL COVERAGE FOR WORKING WELFARE FAMILIES - 31 States
(Section 303 of the Family Support Act of 1988, P.L. 100-485)

Alabama
Alaska
Arizona
Arkansas
Colorado
Florida
Georgia
Idaho
Illinois
Iowa
Kansas
Louisiana
Michigan
Minnesota
Mississippi
Missouri
Nebraska
Nevada
New Jersey
New York
North Carolina
Ohio
Oklahoma
Oregon
Pennsylvania
South Carolina
Tennessee
Texas
Utah
Washington
Wisconsin

PAYMENTS FOR OBSTETRICAL AND PEDIATRIC SERVICES - 23 States
(Section 1926 of the Social Security Act)

Alabama
Alaska
Arizona
Delaware
Dist. of Col.
Hawaii
Idaho
Louisiana
Maine
Massachusetts
New Hampshire
New Mexico
North Dakota
Oklahoma
Oregon
Pennsylvania
Rhode Island
South Carolina
South Dakota
Utah
Vermont
Washington
Wyoming

EPSDT - 18 States
(Section 6403 of OBRA 89, P.L. 101-239)

Arkansas
Colorado
Hawaii
Illinois
Indiana
Kansas
Maryland
Minnesota
Missouri
Nebraska
New Jersey
New York
Ohio
Puerto Rico
South Dakota
Utah
Virgin Islands
Wisconsin

PAYMENTS FOR FEDERALLY-QUALIFIED HEALTH CENTER SERVICES - 13 States
(Section 6404 of OBRA 89, P.L. 101-239)

Alabama
Florida
Georgia
Idaho
Indiana
Iowa
Maine
Michigan
Nebraska
Oregon
Pennsylvania
Utah
Washington

PAYMENTS TO DISPROPORTIONATE SHARE HOSPITALS - 46 States
(Section 1923(a)(1)(B) of the Social Security Act)

Alabama
Alaska
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
Wisconsin
Wyoming

The enclosed chart displays detailed information on the statutory effective date, Federal Register and State Medicaid Manual citations of various Medicaid changes enacted during the past several years.

With regard to the nursing home reform provisions, I would like to point out a few factors that affect the implementation of the statute.

- The OBRA 87 represents the most significant nursing home reform since Medicare and Medicaid first began to cover nursing home care. The demands of this reform necessitate a deliberative process and an orderly implementation schedule.

- We have been eager to implement nursing home reform since the findings of the Institute of Medicine. HHS had issued its own NPRM prior to OBRA 87. The statute necessitated modification of some parts and the addition of other regulations. We issued what we could as a final regulation in February 1989, especially patients' rights and quality of care, which were not affected by the new statute. We delayed the effective date until January 1990, and the Congress delayed it further until October 1, 1990. This was because of concern voiced by consumer advocates, industry and Congressional staff that States would need more time to implement. The revised final regulation is to be issued shortly, and it contains some clarifications based on the numerous comments received.

- On PASARR and nurse aide training, the statute directed us to provide guidance to States in the absence of regulations in order to implement the provision. Manuals were issued; proposed rules were published by the date set in OBRA '89; about 2,000 comments were received; and we still hope to publish final regulations this Fall.

- As of October 1, 1990, States and the Federal government will be required to use the enforcement process provided by OBRA 87 that allows for the use of alternative remedies for deficient practices. We expect an NPRM in the near future. On September 1, 1989, through the State Operations Manual we issued survey procedures and interpretive guidelines for implementing the long term care requirements. We have conducted extensive training sessions for our regional office surveyors and our State agency surveyors since surveys will have fundamental changes, such as assessment of patient outcomes.

- Many of the OBRA 87 provisions are difficult to implement and cover extremely sensitive issues. There are many, and often competing, interests involved, from nursing home owners to consumers and both the Federal and State governments. In the case of PASARR, we also involved both State Medicaid and mental health agencies. Our primary goal is to make sure that we do what is best for the Medicare and Medicaid nursing home patients.

IMPLEMENTATION OF MEDICAID CHANGES

PROVISION	SUBJECT	STATUTORY EFFECTIVE DATE	REGULATION	MANUAL ISSUANCES
a. OBRA 87 4104(a)	Extending Coverage to Pregnant Women and Infants	7/1/88	NPRM Under Development	Trans. 7, 7/88
b. OBRA 87 4112	State Payment Adjustments to Disproportionate Share Hospitals	Hospital Pymts. after 7/1/88	NPRM 3/19/90 55 FR 10077	IM 88-1, 5/88
c. OBRA 87 4211	Nursing Facility Quality of Care			
	o Service Requirements	Varies	NPRM 2/2/89 54 FR 5316	
	o Resident Assessment Instrument	10/1/90	NPRM Under Development	Trans. 241, 9/5/90
	o PAS	1/1/89	NPRM 3/23/90 55 FR 10951	Trans. 42, 5/89
	o ARR	4/1/90	55 FR 10951	
	o Nurse Staffing Waivers	10/1/88 (criteria)	NPRM Under Development	
	o Nurse Aide Training and Competency Evaluation	10/1/90	NPRM 3/23/90 55 FR 10938	Trans. 62, 5/89
	o Nurse Aide Registry	1/1/89	55 FR 10938	Trans. 46, 11/89
	o Rights/Restraints/ Transfer/Discharge	Varies	NPRM Under Development	

IMPLEMENTATION OF MEDICAID CHANGES

	PROVISION	SUBJECT	STATUTORY EFFECTIVE DATE	REGULATION	MANUAL ISSUANCES
		o Charges to Personal Funds of Residents	10/1/90	NPRM 3/20/90 55 FR 10256	
		o Facility Administrator	7/1/89	NPRM Under Development	
d.	OBRA 87 4212	Survey and Certification Procedures for Monitoring Quality of Nursing Facility Care	10/1/90	Medicaid Self-Implementing. NPRM to be published in the near future.	Trans. 232, 9/89
e.	OBRA 87 4213	Revisions to Process for Enforcing Quality Requirements	1/1/88 with 10/1/89 for State Laws and Plan Amendments	Medicaid Self-Implementing. NPRM to be published in the near future.	Trans. 43, 6/89
f.	MCCA 88 301	Medicare "Buy-In" Premiums and Other Cost Sharing	1/1/89	NPRM Under Development	Trans. 21, 12/88
g.	MCCA 88 302(b)	Coverage of Medically Necessary Services for Infants	7/1/89	NPRM 3/19/90 55 FR 10077	Implemented via State Plan Review
h.	MCCA 88 303	Special Financial Eligibility Rules for Community Spouses of Nursing Facility Residents	9/30/89	NPRM Under Development	Trans. 39, 10/89
i.	FSA 88 303	Transitional Medicaid Coverage to Working Families	4/1/90 (Ky., 10/1/90)	NPRM Under Development	Trans. 42, 3/90
j.	FSA 88 401(d)	Extension of Medicaid to Two-Parent Families When Principal Earner is Unemployed	4/1/91	FSA NPRM Under Development	

IMPLEMENTATION OF MEDICAID CHANGES

PROVISION	SUBJECT	STATUTORY EFFECTIVE DATE	REGULATION	MANUAL ISSUANCES
k. OBRA 89 6401	Extending Coverage to All Women and Children Up to Age 6 with Income at or Below 133% of Poverty	4/1/90	NPRM Under Development	Trans. 45, 6/90
l. OBRA 89 6402(b)	State Assurance of Adequate Payment Levels for Obstetrical and Pediatric Services	7/1/90	NPRM Under Development	Issued Instructions 3/90
m. OBRA 89 6403	Revision and Expansion of Mandatory EPSDT Benefits For Children	4/1/90	NPRM Under Development	Trans. 4 (Part 5), 4/90 Trans. 3 (Part 2), 7/90 Trans. 67 (Part 5), 7/90
n. OBRA 89 6404	Requires States to Include Coverage for Services of Federally-Qualified Health Centers	4/1/90	NPRM Under Development	Trans. 17, 4/90

Mr. Waxman. Thank you very much, Dr. Wilensky.

I want unanimous consent at this point to have inserted in the record not just your written statement, but the questions that we had sent to you regarding Medicaid issues, dated August 15 and your response to those questions.

On August 15, I sent you 11 questions regarding Medicaid, a design to clarify the administration's position on various bills pending before the subcommittee and I asked that you respond by last Thursday so that members would have time to review your answers for today's hearing.

This morning your office delivered the answers to questions 10 and 11. I would like to know when the subcommittee can expect to receive answers to the remaining questions.

Ms. Wilensky. I don't at this point——

Mr. Waxman. If not in writing, perhaps we can review some of them here, but we did request them in advance of this hearing.

Let me pursue these questions.

Number one from the August 15 list so that we can get down on the record what the administration's position is on each of the six Medicaid initiatives contained in the House budget resolution, and I would appreciate it, even though you have said you are against all of these initiatives in total, to have a yes or no answer in terms of the administration's position.

First of all, does the administration support H.R. 3931, sponsored by Mrs. Collins and Mr. Hyde, which would implement the campaign promise of President Bush to phase in Medicaid coverage for pregnant women and infants with incomes below 185 percent of the poverty level? This bill would make Medicaid available to an estimated 125,000 pregnant women and 88,000 infants in fiscal year 1993, when 185 percent standard is fully phased in; yes or no?

Ms. Wilensky. No.

Mr. Waxman. Does the administration support H.R. 3932, sponsored by Mr. Slattery and Mr. Miller, which would implement another campaign promise of President Bush, to phase in Medicaid coverage for all children and families with incomes below 130 percent of the poverty level? This bill would make Medicaid available to an estimated 156,000 poor 8-year-olds in fiscal year 1991; yes or no?

Ms. Wilensky. No.

Mr. Waxman. Those two of the initiatives are based on the President's campaign promise, and he didn't have too many specific campaign promises. He had a lot of rhetoric about Billy Horton and the flag, but these were two specifics.

The third specific campaign promise I recall was no new taxes. And I gather that the administration has fudged on that issue as well.

I certainly hope Saddam Hussein isn't monitoring this hearing, because he may not believe the President's statements regarding the Persian Gulf either.

Does the administration support H.R. 3933, sponsored by Representatives Wyden, Waxman, Roybal and Rinaldo, which would allow States to cover community, home and community-based services for functional disabled elderly?

Ms. Wilensky. No, it does not.

Mr. **Waxman**. And does the administration support H.R. 3934, sponsored by Mr. Tauke, Chairman Dingell and myself, which would allow States to cover home and community-based services for Medicaid eligible individuals, mental retardation, epilepsy or cerebral palsy?

Ms. **Wilensky**. No, it does not.

Mr. **Waxman**. H.R. 3935, sponsored by Chairman Panetta and Representative Gradison, which would require States to cover hospice services under the Medicaid program? It would make it available to an estimated 40,000 terminally ill Medicaid beneficiaries next year.

Ms. **Wilensky**. No, it does not.

Mr. **Waxman**. H.R. 4080, by Mr. Scheuer and myself, for preventative drugs, physicians' services, low income people infected with the HIV virus, and I gather your answer to that was no, because your testimony indicated that as well.

Ms. **Wilensky**. Yes, that is correct.

Mr. **Waxman**. In your statement, you cite costs as one of the reasons of your opposition to these six Medicaid initiatives. Your estimates are substantially higher than those of CBO, which will bind the subcommittee during its deliberations, and without objection, the summary of the CBO estimates will be inserted in the record at this point.

[The CBO staff estimates follow:]

1990 MEDICAID INITIATIVES PRELIMINARY CBO STAFF ESTIMATES, REVISED SEPTEMBER 10

[Outlays in millions]

	Fiscal year 1991	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994	Fiscal year 1995
Infant mortality (H.R. 3931)	30	125	175	305	350
Child health (H.R. 3932)	55	210	270	415	475
Frail elderly (H.R. 3933)	50	220	245	280	330
Habilitation services (H.R. 3934)	40	170	170	200	270
Hospice (H.R. 3935)	1	4	4	5	6
AIDS/HIV (H.R. 4080) [1]	110	500	570	650	700
Total	285	1,230	1,435	1,855	2,130

NOTE: All fiscal year 1991 estimates assume July 1, 1991, effective date. This is only one quarter year cost. Costs in fiscal year 1992 are approximately four times one quarter year cost in fiscal year 1991.

[1] These estimates reflect the following changes in H.R. 4080 as introduced: (1) Effective dates are moved from January 1 to July 1, 1991; (2) eligibility for early intervention services (section 2) and COBRA continuation coverage (section 5) limited to persons at immediate risk of opportunistic infection (i.e., T-cells of 200 or below).

Mr. **Waxman**. Dr. Wilensky, I would like you to submit for the record a justification for the department's estimates on each of these initiatives.

Ms. **Wilensky**. I will be glad to do that.

[The information follows:]

ESTIMATED MEDICAL BENEFIT IMPACT OF 1990 MEDICAID BILLS

[Federal costs in millions of dollars]

	Fiscal year 1991	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994	Fiscal year 1995	Total, 1991–95
H.R. 3931: Infant mortality	0	110	115	325	345	895
H.R. 3932: Child health	80	290	490	635	775	2,270

ESTIMATED MEDICAL BENEFIT IMPACT OF 1990 MEDICAID BILLS—Continued

[Federal costs in millions of dollars]

	Fiscal year 1991	Fiscal year 1992	Fiscal year 1993	Fiscal year 1994	Fiscal year 1995	Total, 1991–95
H.R. 3933: Frail elderly	0	250	450	600	650	1,950
H.R. 3934: Habilitation services	0	600	800	1,000	1,200	3,600
H.R. 3935: Hospice	0	5	5	10	10	30
H.R. 4080: HIV/AIDS	270	535	625	710	805	2,945
Total	350	1,790	2,485	3,280	3,785	11,690

COMPARISON WITH PREVIOUS HCFA COST ESTIMATES

[5-year costs in millions of dollars]

	1989 5-year estimate	1990 5-year estimate	Change
Infant mortality	1,300	895	(405)
Child health	3,090	2,270	(820)
Frail elderly	3,100	1,950	(1,150)
Habilitation services	4,900	3,600	(1,300)
Hospice	45	30	(15)
HIV/AIDS		2,945	(2,945)
Total	12,435	11,690	(745)

BASIS FOR COST ESTIMATES

H.R. 3931: Major cost stems from section 201 phasing in coverage of pregnant women and infants to 185 percent of Federal P.L. Estimated number of individuals covered derived from March 1989 Current Population Survey [CPS] data, and per capita costs from program data. About 200,000 pregnant women estimated to be added to Medicaid rolls.

H.R. 3932: Major cost provisions are: Mandatory phased-in coverage of children under 18 to 100 percent of P.L., optional coverage under age 6 to 185 percent, and optional additional Medicaid transition coverage under the Family Support Act. Again, CPS and Medicaid program data used to estimate expansions. (Over 2 million additional eligible children could be covered when fully phased in fiscal year 2000.) Transition benefit provision estimates assume an average of 6 additional months elected.

H.R. 3933: Frail Elderly Community Care. Participants estimated from current Medicaid elderly enrollees and data on ADL's from 1984 Long Term Care Survey. Some induced enrollment assumed to be caused by the new benefit. Per capita costs from program data on home health and Home and Community Based Waiver services. Total costs reduced to account for maintenance-of-effort requirement on current state-only spending. Thirty percent of states by dollar volume assumed to elect the optional coverage. These assumptions produce about 175,000 recipients of the new services when fully implemented.

H.R. 3934: Habilitation Services. Major near-term impact of this bill arises from $3.5 billion in current state-only spending in this area (Braddock, et al., University of Illinois.) Maintenance-of-effort would require this amount to be deducted from future spending for FFP purposes, but this provision is thought to be administratively so difficult to implement that the provision would be only partially effective. Thus some cost shifting is assumed to occur. Additional induced costs arise from individuals currently in the community and not now participating in a program of services (the "woodworking" effect.) Finally, savings in institutional costs arise from individuals transferred to community care settings. A dollar-weighted average of 50 percent of states assumed to opt for the new services—higher than H.R. 3933 because of the significant current commitment of state-only funds.

H.R. 3935: Mandatory Hospice Services. Medicare experience with hospice benefit used to project Medicaid utilization rates. A special adjustment was made for persons with AIDS, who are more numerous in the Medicaid population. Unit costs derived from Medicare Hospice Benefit Program Evaluation. Total costs offset for states currently electing the benefit.

H.R. 4080: AIDS and HIV Amendments. The major provision of this bill extends optional ambulatory services (including drugs) to Medicaid financially eligible, HIV-infected individuals with sufficiently compromised immune function. PHS estimates of the number of HIV infected and fraction with T4 cell counts below 500 were used as the base eligible population. Medicaid financial eligibility and participation rates assumed to vary by risk group (IV users versus others) and age (adult versus pediatric), with high rates in the pediatric and IV drug categories. Per capita costs estimated at about $8,000, about half of which is for AZT therapy. States accounting for about two-thirds of AIDS costs (roughly equivalent to four or five largest AIDS states) assumed to elect the coverage. Other provisions with significant cost impact include home and community based services for children with AIDS, costs for which were estimated from projections of pediatric AIDS cases and program data, and disproportionate share adjustments for high-AIDS-volume hospitals, estimates for which were based on the AIDS hospital study of Andrulis (August 1989, JAMA.)

Mr. WAXMAN. You just testified that the administration opposes every single one of the Medicaid initiatives for infant mortality, child care, home and community-based care, hospice care and AIDS.

All these initiatives are critical to the poor. I would be the first to admit that they are modest incremental reforms that would not make much of a dent in either the major health crises facing this country, health care for the uninsured or long-term care.

Last spring the Pepper Commission issued a set of broad reform proposals for addressing both of these crises. As a member of the Commission who supported its recommendations, I went to work for its enactment.

On July 23, Secretary Sullivan gave a widely publicized address in Atlanta on the issue of health care reform. He rejected a Canadian-style solution. He rejected employer mandates. He did not propose any solution, but said he was referring the matter to a departmental task force on which you sit as vice chair.

To sum this all up, the administration is against the incremental Medicaid improvements. It is against either the Canadian approach or an employer-based approach. The Bush administration has not yet introduced any Medicaid initiatives of its own or any health care for the uninsured or long-term care proposal.

I know you have only been in your position for a little over 6 months, but the Bush administration has been in office for nearly 2 years. The administration has certainly made clear what it is against. Could you tell me what the administration is for, other than task forces and advisory committees and study groups?

Ms. WILENSKY. Okay.

The objection of the administration to a number of the Medicaid expansions that you have indicated is not a philosophical objection. The objection is at this time for budgetary purposes. While as we sit here, we know that there is a budget summit hearing going on attempting to see whether there can be some agreement as to how to come up with a $50 billion reduction.

Mr. WAXMAN. They are considering at best a 5 year period in which they are talking about reducing the, or limiting the deficit.

Are you suggesting that you are not going to be for—you, the administration, is not going to be for anything to deal with these problems for 5 years?

Ms. Wilensky. No. Unless one of the things were to come out of the summit, and I have no reason to believe this, I think the only way in which there would be a 5 year prohibition, is if there were to be included in the summit, some sort of prohibition against any new programs during that period.

As you know, the Secretary appointed a task force to look at the issues of the uninsured and long-term care. We have been actively engaged in this effort.

A domestic policy council review was set up early in 1990 as a result of President Bush's direction to Secretary Sullivan to review these issues and to report back to him. We are currently in the process of briefing the Secretary on options and strategies, and the work of the domestic policy council, and its working group, are proceeding at this point.

I am hopeful that by the end of the year we will have a secretarial activity that is underway, and discussions within the domestic policy council. It is much more difficult for me to tell you, or I think for anyone to know, whether the domestic policy council at the end of the year will be prepared, being directed by the Secretary, to make a recommendation to the President. I would hope that early in 1991 that would occur.

But we are living in unsettled times, and I don't know whether that will happen. But it is not an issue that is being ignored or not looked at. I, however, certainly share your frustration that we haven't yet come up with a solution or strategy.

Mr. Waxman. Well, you haven't come up with a solution or strategy to all the problems, but the President came up with two specific campaign promises to cover low income women under 185 percent of poverty and infants for prenatal and infant care and to cover all low income below poverty children under the Medicaid program.

You indicate that one of the difficulties is that increases in Medicaid or Medicaid can cost a lot, and bring about greater inflation in the health care sector.

You have indicated that we have a budget deficit, but didn't the President know in 1988 that we had a budget deficit, and that any increases in services or benefits would presumably have some impact on the cost of health care in this country?

And certainly I guess at that time you realized it couldn't have been much of an impact on cost of the health care sector. If anything, it might well hold some costs down rather than have to pay for the expensive treatment for failure to give prenatal care or cover these children who later are going to come into the health care system with even more severe needs.

Ms. Wilensky. I think that there is obviously no question that the President was aware of the major issues at that time, but the situation has worsened rather dramatically.

Right now what the administration has agreed to and had agreed to as of the summer of 1989, is a 2 year moratorium on further mandates with regard to the States. As I know you have heard, the States are feeling exceedingly stressed financially. The Congress was very active over 1989, and has made some very important, very substantial expansions in Medicaid coverage, and the States are beginning to feel the impact of OBRA 1987 nursing home reforms.

I know I am not telling you anything that you haven't been hearing from the various States about the financial stress that they are feeling. I think that in areas in which there is not a philosophical commitment against a strategy, that you ought not to look to our opposition as opposition for 5 years. I think a 2 year moratorium is what was stated.

Mr. WAXMAN. My time has expired and I am going to call on my colleagues, but I am encouraged by your testimonies, because what I hear you saying is the President broke his promise to the poor people in this country to cover them for prenatal and children's care in order to make a promise to the States, and perhaps he won't keep that promise to them either, and we can go back to the original one.

Dr. Rowland.

Mr. ROWLAND. Let me pursue a little bit infant mortality, which is something that I am really interested in, and the administration does not support 185 percent of the poverty level, 133 percent?

Ms. WILENSKY. Not as a requirement.

As you well know, the States have the opportunity to provide services for pregnant women and young children up to 185 percent, and the Federal Government will provide its full Federal financial participation.

Mr. ROWLAND. Not as a requirement?

Ms. WILENSKY. As a requirement at the present time.

Mr. ROWLAND. Realizing that we have one of the worst infant mortality rates in the industrialized world, 1920 or 1921, depending on who you talk to, and the fact that the Medicaid program is causing distress in the States, as you have already pointed out, and the cost of care is quite expensive, what are your thoughts on what should we be doing to address the problem of our high infant mortality rate if we do not mandate through Medicaid doing that?

Ms. WILENSKY. We have a number of activities that are currently underway, and I think we need to make sure that we are making the best use of them that we can.

We have just recently expanded coverage now to 133 percent of the poverty line for pregnant women and children, and OBRA 1989 requires States to demonstrate that they are using payment rates adequate to enlist the services of obstetricians and pediatricians in a way that will provide comparable access.

We have an initiative underway to try to engage in outreach programs. There is some funding provided to States so that they can have outreach programs. There are indications that in areas where there is already coverage provided up to 185 percent of the poverty line, 15 States have done that already, that it is not only that type of Medicaid coverage which is needed, but a much more coordinated series of activities. And I think that we are making sure that we coordinate between our outreach activities, and making sure we have provider participation. We believe that coordinated care and managed care settings can provide very important ways to make sure that pregnant women and young children are receiving access to the full array of health professionals that they need to see, the nurse practitioners, the physicians, et cetera.

And we think it is very important strategy, not just to get better value, but to get the kind of access needed to the whole range of health care providers.

And finally, there is an area that I have been extremely troubled with as I go around and visit inner city hospitals around the country—and whenever I go out and speak, I try to make sure I have a chance to visit health care facilities wherever I am—are the numbers of young women who are giving birth to babies while they are substance abusers of various types, either alcohol or drug abuse.

I think it is extremely important that we begin to look at that in a much more serious way as a Nation. The Medicaid program currently funds a number of activities for substance abusing pregnant women, and as I mentioned in my testimony, we are actively setting up a demonstration to allow States to come in with innovative ways to provide services to substance abusing pregnant women, including the ability to get around the current IMD exclusion, which does not allow Medicaid to pay for treatment in residential facilities if they are above 16 beds.

So I think that there are a number of activities that we can and should do. A lot of them will require trying to put together the many activities that are now going on, but not always as well coordinated as they might be.

Mr. Rowland. What about the participation of health professionals in the Medicaid program for pregnant women? We hear a lot that many say physicians in rural areas are no longer participating in obstetrical care for women. In some of the urban areas also it is increasingly difficult.

Do you find this to be true insofar as participation in the Medicaid program is concerned?

Ms. Wilensky. Well, we have certainly heard those kinds of reports, as I know you have, and we are now being provided with more evidence than we had previously as a result of the requirements of OBRA 1989 that States demonstrate that they are having payment rates that would produce access comparable to what exists for the non-Medicaid population.

We have been working with the American Academy of Pediatrics and the Children's Defense Fund to make sure that we have their best advice on how to make sure that we are looking at rates that ought to produce comparable access, and what we mean by comparable access.

But there is no question that there has been difficulty in securing sufficient obstetrical participation in the Medicaid program. We believe, at least we hear that liability concerns have been a substantial factor, and we are hopeful that the provisions of OBRA 1989 requiring payment that would produce comparable access, and also the expansion of Medicaid to federally qualified health care centers which has frequently been the source of health care for many pregnant women, will assist in that.

But we have certainly heard that has been a problem in the past, and the anecdotal evidence that has been presented to us supports that.

Mr. Rowland. One other question, Mr. Chairman.

You mentioned a liability problem as something that may be responsible for a decrease in the number of health professionals participating in the care of pregnant women. What other factors in Medicaid might be responsible for them not participating?

Ms. **Wilensky**. Well, we think in the past it may have been a payment rate, which is, I presume, the reason that OBRA 1989 has put in a payment requirement that would produce comparable access.

I don't think there has been any substantial evidence to indicate that there were discrimination problems or other reasons beyond financial reasons to keep physicians out of the program.

However—again, let me stress that we believe that coordinated care strategies, because they provide networks of physicians, can help to ensure access to physicians and other health care providers: nurses, nurse practitioners, et cetera, in a way that is sometimes hard to duplicate in the fee-for-service system. It is not the only way and we wouldn't want to suggest it as the only way, but we think it is an important advantage to make sure that pregnant women have access to the full range of health care providers that they need.

Mr. **Rowland**. So the liability problem is one of the principle reasons you think at this time——

Ms. **Wilensky**. And overall payment rates.

But a part of the reason that the overall payment rate has been an issue has been the increasing insurance premiums for obstetricians.

Mr. **Rowland**. Thank you, Mr. Chairman.

Mr. **Waxman**. Thank you, Dr. Rowland.

Mr. Dingell.

Mr. **Dingell**. Thank you, Mr. Chairman.

Mr. Chairman, I commend you for holding this hearing. I think it is very important that it be done.

I would like to welcome Dr. Wilensky, and say that, Doctor, my questions today are not going to be friendly. I recognize that you did not have a part in much of the matters about which I complain. Mr. Chairman, I would ask unanimous consent to insert my statement in the record.

Mr. **Waxman**. Without objection, that will be inserted.

[The prepared statement of Mr. Dingell follows:]

Prepared Statement of Hon. John D. Dingell, a Representative in Congress From the State of Michigan

Each year, 40,000 American babies die in their first year of life. Thousands of those deaths could be prevented by providing pregnant women and infants ready access to medical care.

Medicaid can provide that access and prevent death and disease. For the past 10 years, in the face of severe cuts to health programs, this committee has fought vigorously to expand Medicaid. We are proud of our accomplishments, which have not been without real struggle and compromise.

We also are disheartened and baffled by the obstructions which two Republican administrations have placed in the path of those fighting to reduce infant mortality. In the early part of the 1980's, the Reagan administration waged war on the poor and reduced child health advocates to protecting the status quo. But this status quo was unacceptable: the highest infant mortality rates of any Western country and among the lowest immunization rates. Indeed, this committee spent countless hours demonstrating to the administration what was obvious to the rest of the world: when 1 out of 33 Americans in the Nation's capitol city die before their first birthday, an epidemic is present.

In recent years, administrations have begun to acknowledge the problem. They even have undertaken to study it by reviewing facts and policies that have been debated in more enlightened quarters during the prior two decades. Regrettably, such study has become a subterfuge for action, and even more distressing, a means of covering up the nature of the problem.

Last spring, I learned that the administration has formed a task force on Infant Mortality and that the task force had developed a report and set of recommendations for tackling the infant mortality problem. I also heard allegations that the administration had squashed the findings and recommendations because they suggested, among other things, expansions of Medicaid in a manner proposed by President Bush during his 1988 campaign and later abandoned.

In an effort to discern the latest and best thinking about infant mortality, my Subcommittee on Oversight and Investigations sought the report from the administration. Projecting its own apparent apathy onto this committee, the administration first questioned whether this committee really had any legislative interest in infant mortality. Our record in Medicaid, childhood immunization programs, maternal and child health, community health centers, and a variety of other health programs reveals the absurdity of that claim.

Having apparently awoken to the legitimate interests of this committee, the administration then pursued 3 months of twisted legal and bureaucratic responses in order to keep from the legislative and public eye important information on preventing the death of babies. Ironically, the White house managed to drag the Justice Department into the issue of infant mortality for the purpose of obfuscating some simple facts. Had the administration ever devoted the same resources to preventing unnecessary deaths that it employed to cover up its inaction, many American families would have been spared untold suffering.

After, news leaks and embarrassing disclosures, the administration finally decided to make available the final draft of the White House Task Force on Infant Mortality—a November 30, 1989 document. The report confirmed the depth and breadth of the problem—America's record on infant mortality is abysmal—and suggested a number of solutions. In this hearing, we look forward to eliciting from the administration its reasons for the long delay in issuing this report and its views on the report's recommendations. Specifically, this hearing affords the administration an opportunity to explain to this subcommittee whether reducing the infant mortality rate is a problem it intends to attack today, or whether it is an issue to put aside until tomorrow.

The hearing also is timely because members of the Budget Summit from both the congressional and executive branches will need to decide whether our national priorities, which include hundreds of billions of dollars to bail out savings and loan institutions, also should include some funding—a few hundred million dollars—to protect the lives of infants.

Delivering healthy babies is a matter of national will. We know how to do it, and we know the costs of failing to act. According to this administration's own figures, 10,000 of this Nation's annual 40,000 infant deaths are preventable with a few straightforward steps.

In the absence of comprehensive reform of our health care system—a problem that the administration seems committed to merely study at the expense of real action—Medicaid is our best hope for our poor infants and for their mothers and siblings. On its 25th anniversary of serving people and saving lives, the program deserves our strong support.

Mr. DINGELL. Dr. Wilkensky, on August 15, 1990, the department provided the Subcommittee on Oversight and Investigations with a copy of a draft of a November 30, 1989, draft report of the White House task force on infant mortality. That was delivered after a request which was made on April 19.

Were any changes made in the final draft of that report, or in that draft which was submitted to us, or does that constitute the final draft of the policies, statements, and the findings which were included in the White House task force on infant mortality?

Ms. WILENSKY. The report that you have was a report I believe as it existed November 1989 that was a working document.

Mr. DINGELL. Yes.

Ms. WILENSKY. There has been additional information that has been available to the department. In July, for example, there were a new set of infant mortality statistics that were released by the department.

This is a working document. I assume it continues to undergo revisions.

Mr. DINGELL. Has it undergone revisions?

Ms. WILENSKY. I believe it has.

Mr. DINGELL. Have there been any revisions?

Ms. WILENSKY. I am not positive.

Mr. DINGELL. Why was the document withheld from the committee?

Ms. WILENSKY. Well, I believe that this was regarded as an internal document being used to provide information to the domestic policy council's work group that was working on this issue, and that it was not regarded as an external document. It was not a complete document and it was part of a working paper.

Mr. DINGELL. Was executive privilege claimed in connection of the withholding of the document from the committee?

Ms. WILENSKY. I don't know.

Mr. DINGELL. It was not.

Ms. WILENSKY. I am not aware that it was, but I don't know.

Mr. DINGELL. On what ground was it withheld from the committee?

Ms. WILENSKY. The only issue that I am aware of is that this was an internal working document. It was not a completed document.

Mr. DINGELL. Executive privilege was not claimed?

Ms. WILENSKY. I have not heard that raised. I am not a part of that particular domestic policy council work group. I work on the uninsured task force and the uninsured domestic policy council right now.

Mr. DINGELL. You should know that the Secretary came very close to receiving a subpoena and finding himself immersed in the contempt process, which I can assure you is not a pleasant process, because of the recalcitrance of the department and the refusal to deliver this document on the request of the committee.

Now, I have some questions.

The New York Times article about the draft appeared on August 6 of this year, and in that article it said, there is nothing politically or intellectually wrong with the draft report, according to the quote of one administration official. He stated, however, it had been sent back for further work.

What was the further work for which it was sent back?

Ms. WILENSKY. I am not aware of that.

Mr. DINGELL. You don't know. Have any changes been made as a result of this requirement for further work?

Ms. WILENSKY. The best of my understanding is that there has been some further discussion. I don't know whether it has been incorporated into changes to the working document.

Again, it is a working and an internal document. Typically, those tend to change over time. I don't know whether this one has, but I know it has been subject to further discussion.

Mr. DINGELL. The statement was made that it was not ready for prime time. Can you tell us why it was not ready for prime time?

Ms. WILENSKY. I didn't make the statement. I don't know what the individual had in mind.

Mr. DINGELL. What was the nature of the work which was requested to change this document?

Ms. WILENSKY. I don't know.

Mr. DINGELL. Have any changes been made as a result of that matter?

Ms. WILENSKY. I don't know.

Mr. DINGELL. Are there any factual inadequacies in the draft which was submitted to the committee?

Ms. WILENSKY. The information is out of date.

As I indicated, it was dated November 1989. I know of additional infant mortality statistics, but I assume there are a variety of other issues for OBRA 1989 legislation that would not have been reflected in November 1989, so I think it was accurate as of the time, but I am sure it is out of date, inaccurate now.

Mr. DINGELL. Let's go through this.

The document indicates that nearly 40,000 babies in the United States die before their first birthday, and that another 400,000 develop a chronic or disabling condition. Has that statistic changed?

Ms. WILENSKY. I assume the July 1990 figures have changed, but I don't know how significant the change was.

Mr. DINGELL. Do you know what the July figures are? How have those figures changed?

Ms. WILENSKY. The infant mortality has declined slightly.

Mr. DINGELL. By what order of magnitude?

Mr. WAXMAN. The record will show that Dr. Wilensky and her staff have both nodded their head in the negative.

Ms. WILENSKY. Slightly, very slightly, yes.

Mr. DINGELL. The document reflects a rate of death at an all time low, but it also indicates that the rate is higher in that of 21 other industrialized nations.

Has that changed?

Ms. WILENSKY. The approximate ranking would be correct.

Mr. DINGELL. So those statements again are correct.

The document also indicates that the decline in infant mortality in the United States slowed in the 1980's. Has that changed?

Ms. WILENSKY. Well, I assume it wouldn't have changed in 1990.

Mr. DINGELL. Now, the document also says that the picture is particularly bleak for black infants and that nearly twice as many black babies die as white babies during the first year of their life.

Has that statistic changed?

Ms. WILENSKY. Not in a substantial way.

Mr. DINGELL. In 1987, the black infant mortality rate was the same as white infant mortality rates of 25 years earlier. Has that figure changed?

Ms. WILENSKY. I am sure it didn't change after 1987.

Mr. DINGELL. Do you agree or disagree with the statements which I have made up until now?

Ms. WILENSKY. The substantive figures that you have read I believe are substantially correct.

Mr. DINGELL. Now, infant mortality and disability, are they intractable problems, or can they be dealt with by expenditures of moneys and good programs to provide for the health of infants, or should we just say that there is nothing we can do, God decrees, and the child will go to his reward at an early time?

Ms. WILENSKY. They are difficult problems. I certainly would not suggest that we say that there is nothing we can do about them, nor would I suggest that there is nothing that we have been trying to do about them.

Mr. DINGELL. The record indicates that this country has the knowledge necessary to save 10,000 additional infant lives each year. Is that a factual statement?

Ms. WILENSKY. I have no idea. I don't know what that statement was based on.

Mr. DINGELL. That we can do it through devices like prenatal care, postnatal care, nutrition, and other steps which can be taken to give the infant both a better chance of starting out when born and also a better chance of surviving after birth.

Is that a fair statement or not?

Ms. WILENSKY. There are a number of things that we know that substantially assist the likelihood of survival, such as not smoking, not drinking alcohol, not abusing drugs, having good nutrition. The question of how to translate that into behavioral change is usually more difficult.

Mr. DINGELL. Education of the mother is a component of that; is it not?

Ms. WILENSKY. It is generally one of the components.

Mr. DINGELL. Now, other nations have significantly reduced infant mortality. I gather that they have done this by good prenatal care, good postnatal care, health promotion, education, illness prevention, dealing with problems, smoking, drugs, alcohol and so forth, have they not?

Ms. WILENSKY. I don't know that we know exactly why other countries have had better success than we have. They certainly use different kinds of programs in terms of some of their prenatal and postnatal care, but it is not that this is an easy problem to solve.

There are many places in the United States, many areas, cities, States that have expended great efforts that have substantially expanded the amount of prenatal and postnatal coverage that they provide and that frequently continue to have difficulties with infant mortality.

It has been a difficult problem for us to resolve.

Mr. DINGELL. You are telling me that nobody in that vast institution of the Department of Health and Human Services knows why the United States lags these other countries in infant mortality?

Ms. WILENSKY. I suppose that it is not a question of a single reason, but a whole set of complex reasons as to why that happens.

Mr. DINGELL. Do they have any idea what these complex reasons might be?

Ms. WILENSKY. I suppose they do.

Mr. DINGELL. They do. But you can't tell us what they are?

Ms. WILENSKY. I think it would probably be more appropriate to have somebody from the Public Health Service who is a specialist in that area give you that.

Mr. DINGELL. Well, the interesting thing is that we requested this very information from the Department of Health and Human

Services in April, and we got it in August, which is a difference of 4 or 5 months.

Didn't the inquiries of the committee trigger some interest on the part of the Department of Health and Human Services as to what the answer to these questions might be?

Ms. WILENSKY. I am not in a position to respond.

Mr. DINGELL. Is there anybody down there who might know the answer to these questions that we could have come talk to us?

Ms. WILENSKY. I suppose the Secretary might or the Assistant Secretary for Health. Probably the Assistant Secretary for Health is an appropriate person.

Mr. DINGELL. You told me the Secretary might. Is there an Assistant Secretary who might that comes to your mind?

Ms. WILENSKY. The one in charge of the Public Health Service.

Mr. DINGELL. You think he or she might know?

Ms. WILENSKY. He should be able to help.

Mr. DINGELL. You don't think the Secretary would know?

Ms. WILENSKY. I am sure the Secretary would also.

Mr. DINGELL. Now, this statement has been made in a study by the Institute of Medicine: the high economic cost of infant mortality can be reduced. The Institute of Medicine is, by the way, a responsible organization, is it not?

Ms. WILENSKY. I am a member of that, yes.

Mr. DINGELL. The Institute of Medicine found that every additional dollar spent on prenatal care for high-risk women saved $3.38 cents in total costs of care for low-birth-weight babies. Is that a fair statement?

Do you agree or disagree?

Ms. WILENSKY. Well, as an economist who has frequently engaged in such studies, I don't know how precise those figures are. Prenatal care is generally regarded as one of the more effective, cost-effective areas of expenditure.

Mr. DINGELL. Well, let's put it this way, do you disagree?

Ms. WILENSKY. I don't have a basis for disagreeing.

Mr. DINGELL. You don't know?

Ms. WILENSKY. I don't know the accuracy of that particular fact that you just read.

Mr. DINGELL. Does it sound fair to you?

Ms. WILENSKY. It sounds like it might be a little high, but I think prenatal care is cost-effective.

Mr. DINGELL. You think it is cost-effective?

Ms. WILENSKY. Yes.

Mr. DINGELL. Now, extending Medicaid eligibility to more poor women and to infants would bring more high risk infants and women into appropriate care regiments, would it not?

Ms. WILENSKY. Yes.

Mr. DINGELL. And so we have before us, then, an option of addressing this question of infant mortality just by taking that one step, do we not?

Ms. WILENSKY. It is one way to try to address infant mortality. I think that it is also clear that that is not the only problem.

Mr. DINGELL. Okay. Now, isn't that step recommended at page 55 in the document that the Department was withholding from the committee?

Ms. Wilensky. To the best of my knowledge there were options, there were not recommendations, made in the document.

Mr. Dingell. You don't think there were recommendations made?

Ms. Wilensky. I don't have it in front of me.

Mr. Dingell. Would you be surprised if I told you that I thought there were?

Ms. Wilensky. Not real surprised.

Mr. Dingell. All right.

Now, the task force report at page 12 identifies expanded Medicaid eligibility as a high priority option, that is an option considered to have the most direct and immediate effect on reducing infant mortality.

Page 55 of the report specifies that expanding Medicaid eligibility means "seeking legislation to raise the mandatory minimum income eligibility level to 150 percent of the Federal poverty level in 1991."

It goes on then to estimate that raising the income standard from 130 to 150 percent of the Federal poverty level would benefit an additional 70,000 women and 50,000 infants in fiscal year 1991. The report observed, and I quote now:

> By providing proper care and services and reducing complications, this option may actually reduce the cost of medical services for infants even though more will be eligible.

Do you agree or disagree with that statement?

Ms. Wilensky. It is usually regarded as one of the cost-effective, most cost-effective to the extent that you have good participation and you did not have other behaviors that were undoing the effects of more prenatal care, like drug abusing behavior and smoking, alcohol abuse, et cetera, then you could well be better off.

Mr. Dingell. And if the mother wasn't struck by lightening or run down by a truck or mugged on a New York subway, that would be a pretty good recommendation, wouldn't it?

Ms. Wilensky. Well, our problems in prenatal care have not been so much being struck by lightening, but 20 percent of births in inner cities are coming to drug abusing mothers.

It is a very serious issue, and I don't say that lightly. When you go to cities that already have coverage up to 185 percent of the poverty line, and sometimes 200 percent of the poverty line, the other 15 being at the State or city's expense, and you are still having 20 percent or higher of births coming in to drug abusing mothers, it is much more complicated than only having additional financial coverage for prenatal care. That is the only point I am trying to make.

Mr. Waxman. Would the gentleman yield to me?

Mr. Dingell. I am delighted to yield to the gentleman. I am well passed my time limits.

Mr. Waxman. One of the questions we have asked in writing is your response to a bill, H.R. 5536, by Representative Towns would have allowed States to cover alcoholism and drug dependency residential treatment services for Medicaid eligible pregnant women and children.

In light of your comment a second ago, what is the administration's position on this bill?

Ms. WILENSKY. As I indicated, the administration at this time is not willing to support any bill that is expending more money as a regular program. What we are doing with regard to the specific issue that you just raised, which is trying to make maximum use of Medicaid coverage are two things.

The first is that Medicaid now covers a wide variety of substance abuse treatment programs, and we have recently sent out a letter to each of the State Medicaid directors going through how Medicaid covers treatment for abusing mothers to make sure they are aware.

Senator Moynihan made it very clear that there is some confusion out in the States. We wanted to try to address that. The second is we believe it may well be cost-effective to bring in pregnant women to residential programs.

As you know, the current IMD exclusion does not allow that. We have, as a result of discussions we have had with the Secretary, now proposed a demonstration. We're actively engaged in that. We expect to have the solicitation out on the streets to the States before the end of the calendar year and have the program operational early in 1991. This would encourage States to come in and give us ideas that would include funding for the IMD solution if they thought that was what it would take in order to get some improved treatment for substance abusing mothers.

We will then assess the outcomes of those three to five States that are engaging in it to see whether or not that is correct. We regard this as a very important area, and we are trying to move ahead even in these very tight fiscal circumstances.

Mr. WAXMAN. What if the States come back and say to you they like the Towns bill. It is going to cost them money, but they think that money is well-spent since they have——

Ms. WILENSKY. I am sure Congress will act appropriately.

Mr. WAXMAN. The administration has to act appropriately as well. You have responsibility in the administration for the health and well-being of the people in this country. It is not just responsibility of Congress. If there are as much as 20 percent of the births in urban areas from drug addicted mothers, wouldn't it make sense to be spending some money to try to attack that problem?

Ms. WILENSKY. Again, the States have some optional coverage of substance abusing mothers now. They have it through the home health waiver program—under Medicaid right now. There are some options available. We would be glad to provide you with additional information for the record. Much more, again, as I have said, than we think some States are aware of.

It is why we have sent a letter to each of the State Medicaid directors to make sure they are aware of the coverage that currently exists. The one main area has to do with residential treatment because of the IMD exclusion, and that is something that we are looking at specially.

It is why we thought it was reasonable to do a demonstration to see whether or not that seemed to have an impact and to the extent that it does, then we would certainly be glad to consider legislation to modify that.

[The following information was submitted:]

All State Medicaid Directors

The Medicaid program is an excellent resource in the national effort to deal with drug addiction and related problems. Because Medicaid's benefits are described in terms of specific services rather than the conditions to be treated, there are often misunderstandings as to the extent that the Medicaid program's benefits can help persons with drug addiction and related problems. I am writing to review the ways that available Medicaid benefits relate to the treatment of these conditions in order to ensure that all States are aware of these possibilities.

A number of primary care services may be used, including physicians' services, clinic services, and pharmaceuticals (e.g., methadone). Additionally, services appropriate for treating addiction may be provided (1) by home health agencies, (2) under home and community-based services waivers, and (3) as part of the EPSDT benefit constellation. A number of States have also used freedom of choice waivers or exceptions to their State plans to implement managed care programs targeted to substance abuse. Case management may be used to coordinate the needed services, and special day treatment programs may be established that combine needed therapy, counseling and other services.

Inpatient hospital benefits may be used for acute treatment of symptoms, detoxification and drug-related medical complications. Rehabilitation services may be provided in a wide variety of settings. These include outpatient programs in hospitals and clinics, and impatient programs located in nursing facilities, psychiatric hospitals, and special units in general hospitals. Rehabilitation services may also be provided in settings that are not Medicaid participating facilities.

Although payment restrictions relating to institutions for mental diseases [IMDs] can affect some inpatient programs for treating chemical dependency, it is important to remember that these restrictions do not apply to any facility that has less than 17 beds. For this reason, it may be advantageous to set up this type program in smaller facilities, even though room and board payment would not be made unless it is a participating facility. Optional IMD benefits are also available in psychiatric facilities for individuals under age 21 and for individuals age 65 and over regardless of the size of the facility.

There are many State and local programs funded by the Office of Substance Abuse Prevention, National Institute on Drug Abuse, and Health Resources and Services Administration. You may find it worthwhile to collaborate with these programs. If your State is interested in expanding Medicaid services in the area of substance abuse treatment, we can support this effort by responding to questions as they arise in developing new programs. Please contact your HCFA Regional Office.

Sincerely,

Rozann Abato,
Acting Director, Medical Board.

Mr. **Waxman**. Mr. Dingell, it is still your time if you want to proceed with some further questions.

I know Mr. Wyden has been waiting patiently. Do you want another minute or two?

Mr. **Dingell**. Mr. Chairman, you have been very kind. I would just like to ask one more question. Why is it that allowing a simple notification or a simple educational program with regard to drugs, narcotics, and alcohol and other abuses of that character stands in the way of recognizing the need to provide adequate prenatal care?

Why is it we can't say that we ought to just do both and to include both within the program, within the Medicaid program?

Ms. **Wilensky**. I don't think there is a question of——

Mr. **Dingell**. I think here you find an obstacle that we both agree should be attacked, and this could be achieved by including the infant and the mother under Medicaid for purposes of giving both prenatal and postnatal care.

Ms. **Wilensky**. Mr. Dingell, I don't think anyone would argue about the desirability of extending prenatal coverage. The States are now required to cover pregnant women and young children up to the age of 6 if they have income up to 133 percent of the poverty line.

They have the option and a number of States have taken that option to go to 185 percent of the poverty line. The issue that the administration has faced is substantially opposition from the States. We are hearing it with regard to the OBRA expansions in terms of coverage, as well as the obstetrical and pediatric rates, and even more so in the nursing home reforms about the implications that has had on the fiscal positions of the States, the increased share of their spending that goes to Medicaid. And what the administration has done is to acquiesce to the National Governors Association's request for a moratorium on further mandates, but the full Federal financial participation is available for States that wish to provide coverage up to 185 percent of the poverty line, and we are encouraging that to occur.

Mr. DINGELL. Well, if this statement is true, three questions come to mind. First, why did the administration refuse to make available to the committee the documents that we are requesting? Second, why does the administration not support the programs that have been discussed by Mr. Waxman and me? And, third, when is it that the administration is going to do something other than give us very friendly, kind statements through respected witnesses like yourself?

Ms. WILENSKY. Let me try to answer all three. I assume the objection to the first was a request of an internal working document that was not yet completed. With regard to the second, the objection has been not on a philosophical basis but one at the present time with the struggle going on to try to reduce the Federal deficit that the administration has not felt able to support expansions in the Medicaid program, in part because of the very substantial expansions that have occurred through over age 7, and more recently through over 8 or 9, but the over age 7 is just in some parts being felt.

The task force that the Secretary appointed on which I serve as the vice-chair has been actively engaged in the spring and the summer reviewing options, briefing the Secretary. There is a domestic policy council that the Secretary heads. There is a domestic policy council work group that I serve on that is undertaking these issues.

I am hopeful by the end of the year or early into next year that there will be at least agreement within the Secretary's task force, but I hope also on the Domestic Policy Council review, but whether or not there will be at that time a position to go forward with the recommendation to the President early in 1991, I don't know.

It would certainly be one that I hope would occur, but these are very changing times and I don't know whether that would occur or not.

Mr. DINGELL. To reduce a large part of your answer to a simple statement, one, you didn't want the committee having the information, two, you are studying the matter and don't really have any plans for addressing it, and, three, I suppose you are sort of hoping the whole business will go away so it doesn't affect the budgetary impact, is that an unfair statement?

Ms. WILENSKY. The last is an extremely unfair statement. I spent the last 10 years of my life worrying about options and strategies to address the uninsured and the poor, and I know at least as well as anyone in the room that they are not going to go away.

Mr. DINGELL. What would you bet that next year if we had similar hearings to this that you wouldn't be back to, say, the same thing again and there will have been no new programs and no new initiatives from the administration? We keep a little thing called a tickler file.

We will issue a statement of this on the anniversary date of this hearing. Mr. Chairman, thank you.

Mr. WAXMAN. Thank you, Mr. Dingell.

Mr. Wyden.

Mr. WYDEN. Thank you, Mr. Chairman. Does the gentleman from Michigan desire any other questions?

Mr. DINGELL. No. I thank both the gentleman from Oregon and the chairman of the subcommittee for their courtesy to me.

Mr. WYDEN. Mrs. Wilensky, welcome.

I appreciate the opportunity also to ask some questions.

I would like to focus on a different area to start with. I am of the view that Medicaid is simply being "ripped off" as far as prescription drug prices are concerned.

I think it is one of the largest expenditures of the program, upwards of $3 billion. The evidence, to me, seems to be real clear is that Medicaid doesn't get the same price as, say, the Veterans Department or big HMO's or big hospitals.

My question to you, to start with, is do you share my view that the Medicaid program is being taken as far as prescription drug prices and if so, how much money do you think we lose unnecessarily because we do not have for Medicaid what amounts to most-favored-nation status to buy drugs?

Ms. WILENSKY. Let me try to answer it because they are different pieces. I don't know that I would use the term having the Medicaid program get ripped off, but I think I would agree that Medicaid has not received the lowest prices that have been available.

They have not received the lowest price that the Veterans' Administration has sometimes received nor large HMO's. There are some reasons for that, but it doesn't mean that changes ought not to be made.

Mr. WYDEN. The administration supports legislation now to make changes?

Ms. WILENSKY. We are currently, in the Department, working on legislation to try to look at this issue of achieving better pricing and achieving savings in the prescription drug area. We think that there are things that can be done that would give us better pricing.

Mr. WYDEN. Let me ask you, because we have you here and you represent the administration, in terms of your own personal viewpoint, how best might this be done, particularly your views with respect to the two approaches that are being compared, one approach known as the best prices approach and the other approach known as the therapeutic equivalents approach?

As to your own personal opinion today, which of those two approaches seems to you to be the best way for us to look at this?

Ms. WILENSKY. I have very strong feelings against therapeutic substitution which I have had——

Mr. WYDEN. Not therapeutic substitution, therapeutic equivalents.

Ms. WILENSKY. Well, it depends on how the therapeutic equivalents is defined. I know that you are going to be introducing a bill. Wednesday is what I have heard, so I obviously have not seen it. I am anxious to look at it. I think that a best price strategy that has some safeguards built in it is a good way to go.

It is basically the way that the large hospital and the HMO's have been able to achieve savings, and it is in a way in an open system as opposed to a closed system, an open system being our current Medicaid system, a closed system being an HMO system, that I believe savings can be assured.

There are reasons why Medicaid hasn't achieved, and Medicaid would have some difficulty in achieving, some of the volume discounts that, say a VA program has, because it doesn't have the very large volumes under a Medicaid open system with lots of individual pharmacies. But I do think it is possible to have a best price program constructed that would in fact achieve savings.

Mr. WYDEN. Well, given that your answer seems to reflect that your thoughts are that a best price system would be a better way to go, would you like to see the best price system accompanied by an open formulary?

Is that something that you think goes hand in hand?

Ms. WILENSKY. Well, an open formulary, now I don't know that it necessarily goes hand in hand, literally open formulary is at one extreme. Whether or not there is something that is substantially open formulary, it is my sense that about 35 States have what are generally regarded as open formularies. Although, I don't know that they would meet the literal definition of an open formulary.

Mr. WYDEN. Do you think a possible middle ground between open and closed in terms of the formulary question would be to have the States have a prior approval process?

Ms. WILENSKY. Well, the States now have a process that typically requires generic substitution unless it is specifically written "prescribe as written," so I think it depends on precisely what you are looking at.

I am concerned about strategies that would take away the options now of States to cover prescription drugs as they see fit. As you know, because prescriptions drugs are an optional benefit, States can cover to as wide an extent or to as narrow an extent prescription drugs as they see fit. I would not want to take away the States' right to do this, so I think it is really within that context.

There are formularies that exist and they exist because the State has the ability to provide coverage to as many drugs as it sees fit.

Mr. WYDEN. Does the administration believe that generics should be required to give the Medicaid program the best price, too?

Ms. WILENSKY. Well, I think the administration is regarding multisource and single-source drugs as both areas for savings and that savings ought to be achieved in both areas. We are looking at strategies to see precisely how to go about getting those savings.

They may not necessarily be done in the same way best, but they are both areas in which we expect to see savings and we are trying to develop legislation that would produce savings in both areas.

Mr. WYDEN. When do you all foresee sending to Congress your approach to dealing with the question of Medicaid purchasing medicine?

Ms. WILENSKY. Well, I don't know that we have a precise date. We are trying to very soon, things being what they are in this area, come up with legislative strategy that would outline the way we believe it would be best to achieve savings in terms of both single and multisource drugs. But I don't have a time for when a bill would be introduced or legislative language, but we hope to be able to come forward with the legislative strategy in the not-too-distant future.

Mr. WYDEN. Does HCFA support the proposals that are now being offered by OMB? OMB has got, I guess, several different proposals.

Ms. WILENSKY. Well, we have been working with OMB on a number of proposals, and we are continuing to develop some of the specifics as they also develop some of the specifics, and I think that will continue, and appropriately so at some time, but we are working on some of our own specific strategies, but keeping them advised of what we are doing.

Mr. WYDEN. Let me turn to another area just very quickly. I appreciate Chairman Waxman giving me the time.

As you know, we have got the data bank finally up and running.

Ms. WILENSKY. September 1.

Mr. WYDEN. Perhaps the longest running battle since the Trojan war. I think it is very good news in terms of health quality, but I think there are some other things that we can do to look at the underpinnings of the system. In some hearings that I chaired, Kusserow gave us evidence that the State medical boards are having trouble getting information early enough when they get the first signal that a physician is in trouble or incompetent or misdiagnosing or something of that nature.

I have introduced legislation, H.R. 5451, that would take steps essentially endorsed by Mr. Kusserow requiring that PRO's notify the State medical boards when the first sanction notice is sent a physician, requiring Medicare to notify the State medical boards when a provider is excluded from the program, and also requiring State Medicaid agencies to notify the boards when a provider is excluded.

Is this the kind of legislation again just—you haven't had a chance to review it, but in terms of the concepts, it seems to me again to be something that would have little or no cost and would help significantly in the quality area.

Mr. Kusserow essentially brought it to our attention in some hearings earlier this year.

Ms. WILENSKY. Well, we would like to work with you in making some modifications. The general issue raised, which is earlier sharing of information, is not anything that we have any objection to. There were a couple of areas, as I understand it although I have not seen the legislation, that had to do with the fact that the information seemed to go only one direction, which was from the PRO's out.

We would like, for obvious reasons, the sharing of information to go in both directions. We think it would be very beneficial. Having the PRO's get information would help as well. However, we weren't quite sure whether some of the information that was being asked for from the PRO's would conflict in terms of requirements for data confidentiality. But, again, I think these are areas that we could work with you on. Finally, there was some confusion about what the earliest findings meant, but on the general concept of having an earlier exchange of data between the PRO's and the medical review or the data bank, we do not have a problem and would like to see whether we can't work with you to modify that.

Mr. WYDEN. Let me ask you just one other, if the chairman will let me, what is the status of CLIA?

Ms. WILENSKY. Well, that is something I can probably tell you a lot more about than other things since I pay very close attention to it. We are well along in three out of the four regulations associated with CLIA-88.

The first one, which defines the regulation by complexity of testing, had an initial closure data for comments of August 20. We have been besieged with requests to extend the comment period, which we did at the very last moment, although it was not clear to me that lack of response was a particular problem. But there was a sense that a lot of people wanting to respond to this hadn't gotten to us.

That closing date is now September 21. When I was in Baltimore about 10 days ago, we had 20,000 responses as of that point, and we normally don't get a lot of responses until the very end of a closing period. The user fees and the survey process are both published as a proposed rule.

We have the fourth one that is in circulation and has not yet in fact been published as a proposed rule. The closing periods for comments on the two proposed rules in October. Probably the major area of concern that we have is the enormous volume of responses. As you know, we are required by law to respond to each of these comments.

There are, however, a lot of issues that have been raised, a lot of concerns that have been raised, and we believe that a number of the comments that we have received will be very helpful in terms of going back and making some modification to the regulations that were proposed, concerning the specific tests that were included, the number of categories that we included, the personnel requirements, and the personnel requirements matching the classification of tests.

There is some concern on our part about the use of the user fee since there is not an obvious ability to make use of the funds before the regulation is fully implemented, yet there is need for funding as we go along in that process. We are looking at this issue of timing for the user fee and the needs of CLIA.

Ultimately, it will not be a problem. Ultimately it will be a self-funding mechanism, but in the interim, there are some concerns that have been raised. Both the enforcement provisions and the actual regulation will probably have substantial revision from the proposed rules.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Wyden. Dr. Wilensky, I am obviously disappointed that the administration is not supporting the

President's promise on women and kids, and perhaps I was a little harsher than I might otherwise have been in my comments earlier expressing that, but your argument is that there is a State concern about the mandate and the administration, for that reason, has pulled back.

On the frail elderly and the habilitation services provisions, as I understand your testimony, the administration is looking to see whether the waivers can permit that to happen.

Ms. WILENSKY. Right.

Mr. WAXMAN. The provisions, though, on AIDS and HIV trouble me because, as I understand the administration's position, the opposition is due to the fact that it is a disease specific requirement in Medicaid that we give early intervention drugs to keep people who are infected and who are poor enough for Medicaid from becoming disabled where they would then be eligible for Medicaid for all the hospital services and acute care services to treat full-blown AIDS.

Obviously the administration can't do anything there by way of any waiver.

Ms. WILENSKY. Correct.

Mr. WAXMAN. There is no State option. The amendment is drawn so that persons not only infected, but the T-cell level are low enough so that it is likely that they are going to get full-blown AIDS in a very short period of time, at which point we are going to end up paying for them for acute care services, if this amendment were drawn not just for AIDS specific, but more broadly would the administration be satisfied or would the administration then be opposed because it is too broad an expansion of Medicaid?

Ms. WILENSKY. Well, the issue about the disease specific is one that has existed, as I am sure you are all too aware, for sometime. It was an issue that, when I was providing some technical assistance to the AIDS Commission, came up a number of times as to whether or not expanding coverage on a disease specific basis is something that was desirable for the community, broadly speaking, to engage in, and I think that there has been a lot of concern that doing this on a disease specific basis is a precedent that——

Mr. WAXMAN. So let's do it more broadly. We will allow preventive intervention in cases where Medicaid will treat the person when the disease manifests itself in a relatively short period of time thereafter. I don't know of any other illness where we can intervene so successfully as we can with HIV.

Ms. WILENSKY. If it were phrased like that, obviously the objection that it is disease-specific goes away. I think the second issue that has been—or response that I have heard discussed is that there has—the President has recently signed the Ryan White AIDS bill which will provide at least to the areas that have been hardest hit some additional funding and that while it doesn't completely overlap with this, it will provide some additional funds to particular areas and therefore perhaps make this somewhat less necessary, but there has been heard, at least, the concern about disease specific expansions.

It was an issue that was raised when the catastrophic legislation was discussed, in general whether to go disease specific or not, and it has been an issue that I have heard raised in this area, but I can't promise you that if you weren't to rephrase it that you wouldn't get at precisely what you are saying.

Mr. WAXMAN. I understand. I find it is very frustrating and shortsighted if we are going to end up saying in a relatively short period of time through Medicaid, not just through State intervention, for those very same individuals—I guess we can't get the Congressional Budget Office and your budget people to see the cost savings impact. It seems to me obvious.

Ms. WILENSKY. I have not seen anything that suggests cost savings. All the estimates that I have seen either from the Department or CBO indicate positive costs.

Maybe if we can be convinced——

Mr. WAXMAN. I suppose if you think it through because some of these people can get AIDS and not require hospitalization, some of these people may die faster, but it seems to me intuitive and obvious that if someone is moving in a direct line after the infection and the lowering of the immune system toward a full-blown AIDS and pneumonia that you have the ability to keep them from getting pneumonia or full-blown AIDS, you would do that rather than wait until they get it to pay for it.

We are not talking about a vague sort of preventive service over a longer period of time, but one that has a relatively short time frame. Well, anyway, I guess I just—it seems to me whichever way we phrase it, I can't take seriously this disease specific objection.

It just sounds to me like an academic statement that has nothing to do with the reality. It sounds to me like a reason to oppose it, and if there weren't that reason, there might be another one. I might ask you to comment.

Dr. Rowland.

Mr. ROWLAND. Mr. Chairman, I suppose that if you delay the onset of the disease that the person would be productive longer, which would contribute significantly to the economic well-being of our country, and the taxes they pay in and certainly if you delay the onset of any disease, if you delay our deaths, eventually some time we are going to contribute a lot to society, so it seems to me a reasonable thing to assume that if we delay the onset of that disease that it will certainly cost less in the long run to do that, but let me just ask—I know we are here to talk of these particular pieces of legislation, you have had a lot of comments. I have had a lot of comments about that, too, from more doctors than I have heard about other things.

Ms. WILENSKY. I am sure.

Mr. ROWLAND. Are you hearing more and more criticism, are you hearing from more and more health care providers about increasingly micromanaging the deliver of care? I know that I am hearing this, and a lot of frustration, particularly in the Medicare program as well as the Medicaid program.

What do you see as the end point? I mean, where are we headed with what we are doing?

Ms. WILENSKY. I do hear that, and it concerns me a great deal because having these programs, Medicare and Medicaid, function well is a first requirement to having good programs. Innovative policies aren't going to help much if you don't have basic programs that are functioning well, and trying to make sure that the programs function well and making them more understandable for the elderly and the physicians and the hospitals has been a major goal that I have had.

I think there are some things that we are doing and that will happen anyway that will relieve some of the frustration. There are a number of changes that were made in the Medicare program relating to the physician payment reform that will make the program more uniform and easier to understand for physicians.

Now, some of those who are going to be having reductions in payment may not be too pleased about that, but some of the anomalies in the historical charge, concerns about low payments to rural areas, variations that seemed inexplicable, difficulties understanding the maximum allowable charge that Medicare would allow above a physician's otherwise reimbursable rate, a lot of those will change as the physician payment reforms start becoming much more uniform, much more easier to understand.

And I think that will help because I think it will make the program more understandable. We are also trying to review some of the paperwork and some of the forms to see whether we can't make them understandable. We are doing a number of activities associated with making payment through the carrier reform process. We are trying to relook at the way Medicare pays physicians and hospitals through its fiscal intermediaries and carriers to see if we were designing that system in 1991 instead of the one that we adopted in 1965, whether we might not do things somewhat differently to reduce some of the variations that exist across the States that cause a lot of frustration and that seem to have a sense of inequity.

In a more global sense, though, it is one of the reasons it is not the only reason, but it is one of the reasons—why I am trying to promote coordinated care strategies of a wide variety, not just HMO's, but preferred provider organizations, networks of physicians that have a physician as the primary manager, and other kinds of strategies. If if we don't get our people or the Medicare population into plans of health care of some sort, I see as the alternative that we will probably have more and more micro management of utilization along with Government price setting, and that concerns me.

And I regard the movement into a variety of coordinated care systems to be a preferred strategy. I think in the short term there are things we can do to reduce the frustration level of physicians by trying to have an easier to understand, more uniform program, and where we can, responding to some very legitimate concerns.

One of the demonstrations that we are going to be engaging in in a few States is to have more information known about some of the carrier screens, the parameter screens that are used for medical audit because we know that has been an area that has caused a lot of frustration for physicians.

There has been concern in the past that if those screens were known, physicians who are above the screen would go below, but physicians who were below the screen might also come up to the screen, and that has raised concerns about the cost of the program. What I have asked HCFA to do is to undertake a demonstration in a couple of sites where we make more information known, and ob-serve what happens, seeing whether or not we get the undesirable change as well as the desirable change in an effort to see whether we can't respond to some legitimate concerns that have been raised by the physician community. So, I think that there are ways that we can respond to those concerns.

I am very concerned about some aspects of CLIA. We have been inundated with comments and letters as well as the financial comments in making sure that we can come up with a final regulation that responds to the consumer and patient protection that was obviously the intent of the legislation in a way that doesn't impose unreasonable burdens and costs on to the whole system, ultimately impacting the very people we were trying to help.

Mr. ROWLAND. Mr. Chairman, if I may, just one more comment. You are quite aware of the problem in my own State of Georgia and what is taking place there.

Ms. WILENSKY. Quite aware.

Mr. ROWLAND. The comment has been made that there are going to be increasing numbers of physicians dropping out of the Medicare problem because of what is going on there, but then it was stated there is no statistics to prove that.

I can tell you that I believe in talking with physicians, and I have an article here I want to give you from this past Sunday's paper that there are many physicians that are right at the point now of dropping out, and they are beginning to do it. And I have a real concern because I think that you will see from this article that a lot of people are going to be out there without any physician to take care of them, and I am really very concerned about that.

So I want to let you know the problem in Georgia is not as rosy as some people might think that it is, looking at statistics. I just want to make that comment to you.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Dr. Rowland.

Dr. Wilensky, we did send a letter to you on August 15 with a number of questions. We received a response, questions 10 and 11. I reviewed with you what amounts to question one and all of its sub parts.

We would like you to respond to the rest of the questions in this letter for the record, and we would like you to respond by September 15, which would be a full month after the letter.

Ms. WILENSKY. The only ones where we will have any difficulty were some that were more concerned with budget summit issues. We will indicate if there are questions we cannot respond to, but in the kinds of questions that you were asking orally, we certainly can respond to them and will.

Mr. WAXMAN. Well, we would like you to answer these questions as best you can, be as helpful as possible to us, especially for the record.

Let me also indicate in closing that Chairman Dingell, who has been around this institution for many decades now, is usually right in his predictions. I hope he is wrong when he indicates that a year from now we will be meeting and talking about why the administration isn't supporting anything constructive by way of specific initiatives to deal with these great problems for the poor.

I know of your personal commitment to making good health policy in trying to deal with these issues, and if we are faced with that dilemma next year, I am confident it wouldn't be because you haven't tried within the administration to figure out some ways for us to move forward, so we will look forward to working with you, the administration, and everyone who was concerned about how we deal with those people in our society who are left without access to health care, those who are below the poverty line and, unfortunately, many who are above the poverty line as well.

Thank you very much for being with us.

Ms. **Wilensky**. Thank you.

Mr. **Waxman**. That concludes the hearing, and we stand adjourned.

[Whereupon, at 3:41 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[The following material was submitted for the record:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

The Administrator
Washington, D.C. 20201

SEP 21 1990

The Honorable Henry A. Waxman
Chairman
Subcommittee on Health and
the Environment
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Waxman:

At the hearing before your Subcommittee on September 10, you asked me to respond to the balance of the questions you had sent on August 15.

Attached are responses to those questions to which I did not previously respond or which were not discussed at the hearing.

I hope you find this information helpful.

Sincerely,

Gail R. Wilensky, Ph.D.
Administrator

Attachments

Budget Summit Proposals

You asked about certain Medicaid proposals submitted to the budget summit negotiators. I am not involved in the budget summit negotiations, and cannot speak to whatever specific proposals may be on the agenda. However, since my arrival, I and my staff have discussed a number of options and approaches to constraining Medicaid/Medicare growth rates in a responsible fashion. My emphasis in these discussions will senior Department and Administration officials has been to assure equity, access, and quality of care.

H.R. 4181, the Medicaid State Share Protection Amendments of 1990

H.R. 4181, introduced by Mr. Cooper, would allow States the freedom to finance their share of medical assistance costs through taxes of their choice. Also, it would allow donated funds to be used as part of the State's share of Medicaid spending with two limitations: the donations cannot amount to more than 10 percent of the State's Medicaid spending, and donations cannot be more than 10 percent of the donating facility's gross revenues.

We understand the motivation of this measure in trying to encourage voluntarism. However, we must oppose this bill because it would permit States and hospitals to increase Federal Medicaid spending across-the-board by 10 percent, without any guarantee that State spending would increase equally, and without requiring, increases in services provided or beneficiaries covered.

As you know, we published an NPRM on February 9, 1990, that would require States to offset the revenues derived from all provider donations from Medicaid expenditures prior to calculating FFP. The regulation would provide similar treatment for revenues derived from taxes applied uniquely to providers. The objective of this policy was to assure FFP would not be affected by States' use of tax or donation programs.

However to respond to concerns such as those expressed by Mr. Cooper and many others, HCFA is developing an alternatives to the policy presented in the February 1990 NPRM.

We are looking at these issues to assure that our policy can serve both States' and HCFA's needs. HCFA has contracted with several prominent health economists to conduct a one-day conference on September 24 to assist HCFA staff in the analysis of the system-wide impacts of alternative approaches -- legislative as well as regulatory -- for donated funds and tax revenue approaches.

H.R. 4516, Disregarding German Reparation Payments From Post-Eligibility Treatment of Income Under the Medicaid Program

H.R. 4516, introduced by Mr. Weiss, would disregard, for purposes of computing the post-eligibility income of individuals who are institutionalized or receiving home and community-based services, reparation payments made by the Federal Republic of Germany to Holocaust survivors.

In general we oppose so-called "income disregards" and are concerned about the precedent established by H.R. 4516. However, in view of the bill's subject matter, we will be conducting an in-depth review of this particular legislation.

H.R. 4518, The Medicaid Home Respiratory Care Act of 1990

H.R. 4518, introduced by Mr. Wyden, would require States to extend Medicaid coverage for home respiratory care to ventilator-dependent children and adults who, but for this care, would require hospital or nursing facility care.

I am concerned about access for these children to high-quality, cost-effective care. However, services are available through several existing authorities:

> The Tax Equity and Fiscal Responsibility Act of 1982 allowed States to provide home care to disabled individuals 18 years of age or younger through regular State plan services. The estimated cost of caring for the child in the home may not be greater than the estimated cost of caring for the child in the appropriate institutional setting. As of September 1989, 18 States had implemented this section 1902 (e)(3) option.
>
> Also, OBRA 1987 authorized States to include as medical assistance respiratory care services for any individual who:
>
> o is dependent on life support at least 6 hours a day;
> o has been so dependent for at least 30 consecutive days (or that time authorized under the State plan, whichever is less) as an inpatient;
> o but for the care at home would need it in a hospital, nursing facility or ICF/MR and would be eligible for payment under the State plan;
> o has adequate social support services to be cared for at home; and
> o wishes to be cared for at home.
>
> As of September 1989, 6 States had chosen this option.
>
> States may also provide service to these individuals in their homes under home and community-based service waivers.

In that context, this bill is an unnecessary mandate of what is already optional under Medicaid, and violates the no-mandate agreement with the National Governors' Association.

H.R. 5067 The Patient Self-Determination Act of 1990, introduced by Mr. Levin and Mr. Swift

On July 20, 1990, I testified before the Senate Finance Medicare and Long-Term Care Subcommittee on a similar bill introduced by Senator Danforth. Attached is a copy of my statement for the record which describes my position. We are willing to work together to fashion cooperative programs that educate the public about living wills.

SUMMARY STATEMENT OF GAIL R. WILENSKY, PH.D.
JULY 20, 1990

I commend Senator Danforth and the Subcommittee for raising the complex issue of living wills and other advance directives for discussion. We share the goal of making health care consumers more informed about living wills and their treatment choices. However, we have several concerns about how S.1766 would accomplish this objective.

- We do not believe the Medicare Conditions of Participation should be used for a purpose significantly removed from their primary objective of ensuring that quality care is rendered in a safe environment.
- We are concerned that the bill does not provide adequate safeguards for poor and vulnerable patients.
- We are also concerned that financial assistance for the medical care of the poor would be jeopardized if States do not enact living will laws.
- Finally, we believe that States are better equipped than the Federal Government to conduct effective public education campaigns for their citizens about advance directives.

Improving public awareness about living wills could be better accomplished without linking it to a Federal requirement. We need to develop a coordinated package of informational activities that will effectively inform the public about living wills.

We could consider establishing a national 800 number. States could also provide information at various points of contact with their citizens, such as when people apply for drivers' licenses. We could also work with professional groups like the AHA and the AMA to encourage voluntary efforts. For example, informational material could be made available in waiting rooms; physicians could participate in continuing medical education seminars to encourage discussion of advance directives with their patients.

Community, advocacy, trade, and union groups can be enlisted to spread the word on living wills through their regular newsletters, as can other Federal agencies.

HCFA will do its part by providing informational materials to our beneficiaries through the next update of the Medicare Handbook and through our new beneficiary education campaign. We will also consider other options, such as "check stuffers", which we often include in Social Security checks to provide important information to our beneficiaries.

I want to reiterate my strong support for making the public more aware of the importance of advance directives. However, action by the Federal government regarding their use should be carefully and cautiously considered. Any Federal requirement should not result in a tension or pressure that is inappropriate in personal treatment decisions. We can, however, work together to fashion cooperative programs that educate the public about living wills.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss advance directives, such as "living wills," and their role in making personal health care decisions. The recent, highly publicized Cruzan decision by the United States Supreme Court has elevated the importance of living wills in the public mind.

As we move into the 1990s, medical science and technology are performing life saving and sustaining treatments that were unthinkable a few decades ago. Decisions not necessary twenty years ago have now become commonplace in the hallways of our hospitals and nursing homes. These health care decisions affect our entire population, not just the elderly.

The growing use of sophisticated medical services increases the likelihood that individuals will have to make difficult decisions about whether to prolong care. Providers of health care recognize that these decisions may place them in a troubling position from an ethical and legal standpoint. In this health care environment, living wills and other advance directives assume an even greater importance.

Background

Before the recent Supreme Court decision, the importance of living wills was slowly being acknowledged across the nation.

Most States recognize living wills, durable powers of attorney and other forms of advance directives as valid written documents expressing an individual's fundamental right to make choices about health care. A living will is a written document that instructs physicians to withhold or withdraw care that would prolong the dying process. A durable power of attorney gives another person the authority to make health care decisions if an individual is unable to do so. Over 40 states have laws or court rulings that acknowledge advance directives and define parameters for refusing treatment.

I commend Senator Danforth and the Subcommittee for raising this complex issue for discussion. Decisions regarding the quality of life and death are not easy to deal with. A recent Harvard study revealed that only 15 percent of the patients surveyed had made formal planning arrangements and only 9 percent possess an advance directive. The study also found that when patients are informed of advance directives by their doctor or other health professional they generally receive the material favorably and initiate formal planning.

Proposed Legislation

Senate Bill 1766, the "Patient Self Determination Act of 1989," represents an ambitious effort to highlight the importance of advance directives, and to inform and educate the public about such directives. We share these goals.

I follow a guiding principle: the more knowledge people have about their health care options, the better able they will be to make informed choices.

Your goal of educating health care consumers about living wills is entirely consistent with this principle. Even so, we need to ask questions:

- How can we best advance your goal of informing the public, and

- What role should the Federal government play in promoting public awareness of living wills?

S. 1766 would rely on the Medicare Conditions of Participation for health care providers to achieve these goals. We are concerned that this would manipulate the conditions to a purpose significantly removed from their primary objective of ensuring that quality care is rendered in a safe environment. We also have serious concerns about the adequacy of patient protections and the role of States and State laws regarding living wills. Let me provide a little more detail about our concerns.

Medicare Conditions of Participation

The Medicare Conditions of Participation serve the primary purpose of ensuring that health care facilities provide care that meets professionally recognized quality standards. The health and safety requirements embodied in the Conditions require providers to meet prescribed standards for the health care services they furnish and for the physical environment where they are delivered.

The bill would accomplish its objectives by imposing additional Federal regulation and oversight of Medicare and Medicaid providers of health care. Specifically, to enforce the bill's requirements, we would have to publish regulations amending the Conditions of Participation for providers of care. The new Conditions would describe the procedures and documentation necessary to assure that facilities are in compliance with the requirements relating to advance directives.

Enforcing these Conditions would place the Federal government in a position of judging how adequately providers inform and educate patients about advance directives and their right to make treatment decisions; whether providers properly implement advance directives within the limits of State law; and whether providers appropriately advise patients and staff on ethical issues.

Under this scenario, the Medicare and Medicaid Conditions of Participation would be used to regulate an activity which does not directly relate to the Conditions' immediate goal of assuring quality care. Our enforcement of the Conditions would also be diminished by turning the focus away from the actual care furnished to paperwork documentation. This would be a risky precedent and could encourage further use of Medicare's Conditions to accomplish other unrelated objectives.

Let's be clear about this. The living will issue is too important to do otherwise. If the Congress believes that society will be better served by knowing about living wills, then let's find a way to provide that information directly. We should not obscure the issue by including it in a regulatory process that deliberately stays at arm's length from medical decision-making.

Patient Protections

Our most important concern is for patients. The bill would require providers of care to inform patients of their rights to have advance directives and to document their treatment wishes. We are concerned that the bill does not provide adequate safeguards for poor and vulnerable patients. Providers should not be given incentives to limit possible financial losses by pressuring indigent patients into making hasty decisions about living wills, or by implementing these wills too quickly.

A sick person may be unable to properly consider information about living wills while in a hospital or other facility, at a time of physical and psychological stress. Indeed, a patient could believe that his care might be compromised unless he gives specific treatment instructions. The bill's requirements place an unnecessary burden not only on the patient, but also on the health facility that is required to provide the information.

Conventional record-keeping requirements and Federal survey processes cannot effectively ensure that patient rights are protected under these circumstances.

A living will or other advance directive needs to be considered calmly and logically. A person needs time to think through the implications of such a decision and to obtain any necessary advice and assistance. A discussion of living wills at a time when medical treatment is being sought may only serve to confuse patients or to create anxiety.

There must be better ways to inform people about living wills than through providers of health care. We should look at other avenues to provide information.

The State Role

The bill would also require States to enact legislation regarding living wills as a condition for Medicaid funding. If a State does not does not comply, financial assistance critical to the medical care of the poor could be jeopardized.

Further, the bill would require the Secretary to conduct a national, public information campaign. It is true that a general campaign could increase the public's awareness of the value of living wills. However, such a campaign could not be fully effective without describing the varying legal requirements in each State. But I don't think the States would want the Secretary to interpret their laws. And, because of the diversity of State laws, the Secretary could not assure that an accurate and consistent message on living wills would be delivered from State to State.

States are better equipped than the Federal Government to effectively inform their citizens about advance directives. States know the scope of their laws; they can best interpret these laws, and they can provide better oversight of the laws' implementation.

Unless potentially more effective means of educating the public about living wills have been exhausted, we do not think the intrusive, cumbersome Federal regulatory role the bill would require is appropriate. Other options could better advance the objective.

Other Options

Improved public awareness about living wills could be better accomplished without linking it to a Federal requirement. The government, at the Federal, State, and local levels, funds other educational programs that are not tied to a regulatory enforcement scheme. Why should education about living wills be singled out as a compliance issue?

We need to develop a coordinated package of informational activities that will effectively inform the public about living wills, outside of a forced or coercive atmosphere.

For example, we could consider establishing a national 800 number where people could get answers to general questions and be directed to more specific State information.

States could provide information at various points of contact with their citizens. One that comes immediately to mind is when people apply for drivers' licenses, similar to what is being done for the organ donor program. Such a program could also refer individuals to the 800 number for more explanation.

In fact, States that want to elevate the importance of living wills could mandate that providers conduct information and educational activities as a requirement for State licensure.

We could also work with professional groups like the American Hospital Association and the American Medical Association to encourage voluntary efforts by hospitals and physicians. Informational material could be made available in waiting rooms, again, with a reference to the 800 number. Physicians could participate in continuing medical education seminars to encourage informed discussion of advance directives with their patients.

Community and advocacy groups can be enlisted to spread the word on living wills. These groups, along with trade associations, union organizations, professional associations, and senior groups publish regular newsletters which can target specific information to their constituencies.

Since the Supreme Court decision, we have seen many such organizations distributing information and providing assistance on living wills. We would hope these voluntary efforts would continue and would certainly lend our support and assistance wherever possible.

I intend to see that HCFA does its part by providing informational materials to our beneficiaries. The next update of the Medicare Handbook will contain information on advance directives. I will also see that our new beneficiary education campaign addresses this important issue. Further, we will consider other informational tactics, such as "check stuffers", which we often include in Social Security checks to provide important information to our beneficiaries.

We can also work with other Federal agencies such as the Administration on Aging and the Department of Veterans Affairs, to tap into their routine lines of communication with the people they serve.

The options are endless. It will take a mutual commitment to develop an informational strategy that works, and HCFA will contribute its share to the effort.

Conclusion

I want to reiterate my strong support for making the public more aware of the importance of advance directives.

However, given the sensitivity of the life and death decisions made through advance directives, action by the Federal government regarding their use should be carefully and cautiously considered. Any Federal requirement to advise and inform should not result in a tension or pressure that is inappropriate in personal treatment decisions. We can, however, work together to fashion cooperative programs that educate the public about living wills.

I thank you for the opportunity to discuss this important issue and would be happy to answer any questions you may have.

Testimony of Rep. Tony P. Hall
House Energy Subcommittee on
Health and the Environment
September 10, 1990

Mr. Chairman, I want to thank you for the opportunity to testify before the House Energy Subcommittee on Health and the Environment. I am testifying in support of a permanent legislative exemption from the 75/25 mix enrollment requirement for the Dayton Area Health Plan's (DAHP) Health Insuring Organization.

As you recall, I have been working with the Subcommittee to secure a permanent waiver for DAHP's Health Insuring Organization. DAHP set up this insuring organization in response to the growing health care needs of low- and no-income groups in the Dayton area. DAHP is a locally-conceived Medicaid reform initiative developed to provide capitated pre-paid primary and preventative care on a case-by-case basis. It was designed to provide quality care to Medicaid recipients in a cost-effective and efficient way.

However, a provision in the Consolidated Omnibus Budget Reconciliation Act of 1985 places a 25% non-Medicaid and non-Medicare enrollment requirement on HIO's as with HMOs. I do not question the intent in placing such a requirement on group health provider organizations; to ensure quality care. However, DAHP is unique in that it has a built-in quality assurance. Specifically, is it is sponsored by a local community-based, non-profit Board of Trustees under contract with the Ohio Department of Human Services. In fact, it has been praised by community providers and users as an effective bridge between quality health care and low- and no-income community residents.

I can not stress enough the importance of a permanent waiver. The

75/25 requirement threatens to dismantle DAHP's success in providing health care to low- and no-income groups. The DAHP program is not designed to take on commercial recipients, and a requirement to do so would undermine the doctrine by which this plan has operated; to take care of poor people in the Dayton area.

I am submitting DAHP's "White Paper" which outlines in further detail the program's history and need for a permanent waiver. In addition, I am submitting DAHP's "First Year Summary." I hope after reviewing this issue, you will agree that the 75/25 requirement constrains the success and intent of the plan. Even though remedial measures have been taken -- DAHP has been granted a yearly enrollment mix waiver from the Health Care Financing Administration, renewable for a maximum of three-years -- a permanent waiver is the only answer to ensuring longevity to this important program.

DAYTON AREA HEALTH PLAN
FIRST YEAR SUMMARY

FINANCIAL RESULTS

You'll note from the attached information that the DAHP Program ended its first year in a very positive financial position. This is attributed to the building of reserves in the pre-mandatory enrollment phase of the program and ongoing plan management within budgeted amounts. DAHP was able to return the five percent physician withhold for the eight month period ending December, 1989 (audited), which represented a five percent increase for physician services over and above the Ohio Medicaid fee schedule. Because the five percent increase in physician reimbursement was offered as an incentive to encourage local physician participation and therefore expand access to care, the return of the withhold represents achievement of an important program goal.

OUTSIDE AUDITS AND REVIEWS

Various audits and reviews of the DAHP Program have been undertaken by external agencies over the past year-and-a-half. DAHP underwent a comprehensive quality assurance audit conducted by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (under contract with ODHS) in 1989 and in 1990. The scope of the audit covered compliance with the sixteen JCAHO quality assurance guidelines adopted by ODHS and two provider site audits. Although the final audit report will not be published until fall, DAHP scored a 100 percent on corporate compliance; one provider site scored 100 percent, and the second provider was cited for with a minor deficiency.

The Ohio Department of Health has conducted two quality assurance audits of the DAHP program. These audits covered all quality assurance and utilization review activities as well as provider site audits. Both audits went extremely well with only minor concerns cited at the provider site review. Department of Health officials have been very complimentary of the DAHP program and the emphasis that has been placed on quality assurance and member health education.

Regulatory oversight from the Ohio Department of Insurance and Ohio Department of Human Services include regular monitoring of financial and utilization requirements. Both agencies also monitor member complaints and grievances. There have been no problems identified in any of these regulatory areas to-date.

MEMBER SURVEY

DAHP conducted a mini-member survey of Health Plan Network participants to determine satisfaction with the new health plan and to "test" awareness of several educational efforts (i.e. member's understanding of their right to file complaints/grievances and emergency room procedures). The results of the survey revealed an extremely high satisfaction level with the Health Plan Network (96%). Somewhat as expected, the awareness level about filing complaints and grievances was not as high as we would have liked; 62 percent of members understood their rights and 38 percent did not. Educational efforts will continue in this area. DAHP is currently working with a local university for developing a comprehensive member satisfaction survey covering all 40,000 program participants.

INNOVATIVE PROGRAMS TO ADDRESS SPECIAL NEEDS

One of the motivations behind the development of DAHP, as a locally operated managed care program, was the ability to address the unique health care needs of the

ADC population group. Considered to be the number one health care problem for the ADC population, who are primarily single women in child-bearing years with dependent children, is low birth weight infants and a high incidence of infant mortality.
The high infant mortality rate in the United States, which ranks 19th among developed nations, has received widespread publicity. Local studies for Montgomery County show the infant mortality rate among poor black women to be greater than the local average. Further, low income women, who often lack access to prenatal care and poor nutrition, experience a much higher incidence of low birth weight babies.

Studies have shown the strong link between the health of a mother and her child to be the use of high quality prenatal and obstetrical care. These same studies reach the conclusion that prenatal care is the single most significant factor in determining a newborn's health. Further, prenatal care is cost effective; for each dollar spent on prenatal care, savings between two dollars and ten dollars result. On the average, it costs $400 to provide prenatal care. A low birth weight baby, on the other hand, can easily cost upward of $400,000.

DAHP targeted prenatal care as a high priority issue. Various approaches were examined, and an innovative prenatal care incentive program called BABY'S BIRTHRIGHT was developed. BABY'S BIRTHRIGHT was patterned after a similar program operating in Washington, D.C. and Chicago named "Beautiful Babies Right from the Start." BABY'S BIRTHRIGHT has been endorsed by the Dayton community with over $24,000 contributed in food and merchandise for the program.

BABY'S BIRTHRIGHT provides a coupon book consisting of five coupons requiring a pregnant mother to start prenatal care within the first trimester of pregnancy, continue all scheduled prenatal care in the middle and third trimesters, and keep the baby's and mother's first post-natal appointments following delivery. Coupons are signed by the attending physician, and validated, and then can be redeemed for a $20 gift certificate at a local department store chain or local grocery market chain. The coupons can be redeemed one at a time, or if all five conditions are met, the mother can receive $100 in merchandise.

BABY'S BIRTHRIGHT is available to all ADC recipients of Montgomery County and is administered by DAHP staff. The local March of Dimes has given financial support to the program (a large national March of Dimes grant proposal has recently been submitted by DAHP) and a local television station is promoting the program with public service announcements and news segments. Over 364 coupons have been redeemed in the six-month period the program has been offered. Some mothers are bringing all five coupons in for validation at once to purchase a baby crib or other baby item. Others are redeeming them one at a time and used, for example to purchase food at the end of the month when food stamps are exhausted.

Wright State University (Dayton) is conducting a two-year research project for DAHP to determine the pregnancy outcome as a result of better prenatal care encouraged by the incentives offered under BABY'S BIRTHRIGHT.

EPSDT PROGRAM RECEIVES PRIORITY

Aggressive goals have been established by DAHP for increasing compliance with the EPSDT Program (called HEALTHCHEK in Ohio). Although no definitive numbers exist, ODHS has stated that the compliance rate for HEALTHCHEK screenings for Montgomery County is around 30 percent. The compliance rate for DAHP, is over 45 percent. This noteworthy progress has been made through an organized effort aimed at promoting the HEALTHCHEK Program to members and providers. Letters are sent to all new members and members attaining targeted ages of 1, 4, 7, 11 and 16. Three months later, a reminder letter is sent to all members who have not obtained their physical examination. A printout is also sent to the physician's office so that they may contact the family to encourage care. Additionally, a staff member contacts individual families to discuss the need for preventive care. Emphasis is continually put on the importance of regular check-ups via our quarterly member newsletters, frequent health fairs, and personal contact.

WORKING WITH MEMBERS ONE-ON-ONE

An important feature of a locally managed program is the personal interaction with members to resolve problems, answer questions, and to supplement health information. Four Member Service Representatives handle over 100 calls daily on a variety of concerns ranging from lost identification cards to an inability to obtain medical services. The Member Services staff also attempt to reach all new members for a "Welcome Call" explaining the basic concepts of the program and encouraging members to call if they have problems.

Medical Services Registered Nurses are available 24 hours daily by telephone for assistance regarding medical concerns. They act as a liaison with the Primary Care Physicians to assist members in obtaining medical services and/or interpreting physician instructions. A full time registered nurse Case Manager works intensively with members who have complex, chronic, or catastrophic problems, visiting members in their homes to coordinate care and assisting them in obtaining additional services as needed. Currently, the Case Manager's caseload exceeds several hundred members with special emphasis placed on high risk pregnancy cases and pediatric asthma cases.

Additionally, a full time Health Educator who is a licensed social worker works with members to educate them regarding improvement in their health status and obtaining necessary services. All identified pregnant members are contacted and sent educational materials. They are urged to contact the Case Manager if there are special problems and individual follow-up is made on high risk mothers. During the post-partum period, mothers are sent another packet of health information pertinent to caring for a newborn and themselves during this period.

The Health Educator contacts all new members and members reaching a targeted age of 1,4,7,11, or 16 regarding the HealthChek program and encourages them to make arrangements for a physical examination. A letter is also sent to the Primary Care Physician to encourage their office to also contact the member. If the physical examination has not been completed within three months, a reminder letter is sent.

The Health Educator edits and distributes a quarterly newsletter to all members and maintains a bulletin board in the Member Services office relevant to common health concerns. Staff participates in all local Health Fairs that could be attended by members, offering free literature and other health information on health issues. Personal contact by phone or home visit is made to educate members who tend to use the emergency room inappropriately and assistance is offered to obtain care in alternative settings.

Overall, efforts have been made to identify members with health problems and to establish a means of educating them, assisting them to obtain medical services, and promoting preventative care and early intervention. These efforts are showing results as evidenced by a high degree of high member satisfaction, decreased inpatient hospital days, and dramatic reduction in inappropriate emergency room usage.

DAYTON AREA HEALTH PLAN
RISK SHARING ARRANGEMENTS

Dayton Area Health Plan (DAHP) has various risk arrangements with different providers of healthcare services. For hospital inpatient admissions, DAHP reimburses the hospital based on Diagnostic Related Groupings (DRG's). DRG's represent a single payment to the hospital for all hospital services related to a specific admission. In order to not compromise quality care, guidelines are used to establish cost and time outliers. When these cost or time outlier conditions are met, the hospital receives additional funds to help defray the extra cost of providing the more acute care services. It is important to stress that providers are not at risk for inpatient services. A Pre-admission Certification Program is used by DAHP as a means of managing inpatient expenses, eliminating inappropriate admissions or redirecting treatment to a lower (outpatient) cost setting.

DAHP reimburses physicians based on the Ohio Medicaid fee schedule plus five percent. The extra five percent is then withheld in a reserve pool. The reserve pool may or may not be returned to the physicians at year-end based on the financial condition of DAHP and Board of Director approval. The main reason for the five percent withhold (incentive) is to increase provider accessibility for the Medicaid members. It was rightfully thought that the five percent would encourage more physicians to participate in the DAHP program. DAHP was very pleased to return the withhold for the period ending December 31, 1989.

Five Neighborhood Health Centers sponsored by the combined Health District and operated by local hospitals are paid a capitated per-member per-month dollar amount to provide Primary Care services. The capitation payment rate was developed by an actuary based on state-wide and county specific data utilizing an actuarially equivalent fee-for-service population. The rate also includes a five percent increase which is subsequently withheld and handled in the same manner as the physicians' withhold. On face value, the capitation arrangement shifts the risk from DAHP to the health center. Safeguards, however, were built into the contract so that severely ill members could be excluded from the capitation reimbursement methodology. It is also important to note that no incentives are offered for lower utilization, either in the number of physician visits or hospital inpatient days per thousand members. Another effort to make the capitation reimbursement methodology more fair is the use of a monthly age/sex factor adjustment. This factor adjusts the capitation payments to the capitated providers by taking into consideration historical cost data relating to various age/sex groupings of a like population. DAHP also utilizes capitation and age/sex factor adjustments in reimbursing the participating HMOs in the program.

Other allied health care providers, e.g. pharmacies, chiropractors, etc. are reimbursed at the Medicaid fee-for-service rates. No incentives or disincentives exist for these providers, except that the average turnaround time for claims payment by DAHP is twenty-four days. This is considerably quicker than for Ohio Department of Human Services (ODHS). Problems are also more easily resolved through the locally operated program rather than ODHS.

DAYTON AREA HEALTH PLAN
MONTGOMERY COUNTY, OHIO

I. HISTORICAL OVERVIEW

In response to growing concern from both public and private sectors, the community of Montgomery County set out in 1983 to search for innovative solutions for curbing the exorbitant cost of providing medical care to the county's indigent population. A county task force was formed by the Montgomery County Commissioners and charged with looking at alternative approaches for delivering health care to low income groups.

County Task Force and Feasibility Study

The thrust of task force recommendations was to have a physician-based prepaid system for Medicaid and other indigent populations within the Montgomery county service area. The task force proposal was generally considered "ahead of its time". However, a short time after the task force completed its work, the Greater Dayton Area Hospital Association (GDAHA) authorized a year-long feasibility study conducted by Jurgovon and Blair, Inc. (JBI) of the indigent health care situation in the Dayton area. JBI met extensively with local health care providers and business and community leaders to evaluate needs and attitudes of the Dayton community regarding delivery of health care to low income groups. The JBI study concluded that local physicians were not enthused about a risk-based program but might be persuaded to participate if area hospitals shared a greater portion of the risk. The study further recommended that the best structure for operating a prepaid program was a Health Insuring Organization or HIO.

HIO Defined

As detailed in 42 CFR 434.2, an HIO is an entity that, (1) pays for medical services provided to recipients in exchange for a premium or subscription charge paid by the State Medicaid agency, and (2) assumes an underwriting risk. In general, HIOs are paid a negotiated fixed amount per enrollee per month to underwrite the cost of providing Medicaid covered services. HIOs then negotiate contracts with area providers to actually deliver these services.

The HIO itself is specifically prohibited from directly providing the services. The HIO providers with whom an HIO can contract include HMOs, individual or groups of physicians, hospital outpatient departments, public health clinics, dentists, and other limited practitioners.

By contracting with area providers for the delivery of covered Medicaid services, an HIO acts essentially as an intermediary for the State Medicaid agency. The HIO may contract with providers on a fee-for-service basis, and reimburse them at the same fee schedule levels or cost-based reimbursement levels as those determined and used by the State Medicaid agency.

State Grant Funding

Simultaneous to the formation of the county task force, the State of Ohio was faced with spiraling increases in the cost of health care provided to Medicaid recipients. Statewide, Medicaid costs increased from $32 million in 1966 to over $2.7 billion in 1988. Further, Medicaid accounts for nearly 20 percent of Ohio General Fund expenditures.

The Ohio Department of Human Services, the State agency charged with administering the Medicaid Program in Ohio, sought to lay a foundation for building long-term cost containment systems. Acting upon recommendations from a Governor's task force and special grant funding which was made available, ODHS supported the development of organized health care delivery systems for the Medicaid population in a move to protect and improve the health care available for this underserved segment of the population.

The Greater Dayton Area Hospital Association applied for and received a $500,000 Development Grant from ODHS in 1985. The grant proposal for Montgomery County was to operate a mandatory prepaid enrollment program for all 40,000 county ADC recipients.

In March of 1985 the GDAHA decided it was in the best interest of the community to turn over the project and grant funds to an independent, community-based Board of Trustees.

Dayton Area Health Plan Board of Trustees Formed

A twelve-member Board consisting of hospital, physician, business, and governmental representatives was formed in May, 1985.

DAHP was formed as a nonprofit corporation under the legal authority of Chapter 1702 of the Ohio Revised Code, the Ohio Nonprofit Corporation Law. Its purpose is to develop, implement, and operate a capitated health care delivery system as a federally designated Health Insuring Organization under contract to ODHS, for the Medicaid ADC population of Montgomery County.

Management Company Hired

The DAHP Board of Trustees, in an effort to expedite development of the program, selected a local health care management company on a competitive bid basis to develop the program concept, and to manage the day-to-day operations. All Care, Inc. was selected as the Management company for DAHP because it was a locally operated company and it is a subsidiary of the largest HMO in the Dayton area.

II. DESIGN AND STRUCTURE OF THE DAYTON AREA HEALTH PLAN PROGRAM

As a mandatory enrollment program, Dayton Area Health Plan is both similar and unique compared to Medicaid risk programs developed in other areas.

Under the DAHP Program, Montgomery County ADC recipients enroll with one of three participating health care plans. Two of these plans are locally operated HMOs that have served Medicaid on a voluntary enrollment basis. It should be noted that these two HMOs were not operational when the DAHP program was first conceived. However, when they did become operational it was with the understanding that they would participate under the DAHP program.

Health Plan Network

In order to ensure broad access for ADC Medicaid recipients, Dayton Area Health Plan has contracted directly with community providers. This broad base of community providers form the Health Plan Network which is the third health plan option. The Health Plan Network operates in a subsidiary relationship to Dayton Area Health Plan. ~~The~~ ①

1. The Health Plan Network operates as a traditional fee-for-service delivery system. Through the efforts of DAHA, the number of private practice physicians willing to accept public assistance patients increased by nearly 36%.

Enrollment Process

To ensure that ADC recipients have a neutral, unbiased presentation of their options under DAHP, enrollment of Montgomery County ADC clients is facilitated by an independent enrollment broker who is under contract with Ohio Department of Human Services. A local minority-owned consulting company was hired as the DAHP Enrollment Broker.

The enrollment process was designed to coincide with the six-month ADC redetermination of eligibility process. As ADC recipients come to the County Human Services Department for their six-month redetermination, they are directed to the Enrollment Center which also is housed in the same county building.

Recipients receive advance information about the DAHP program and enrollment process in their redetermination materials. Once presented at the enrollment center and their active ADC status validated, recipients review materials on the three health plan options and watch an eleven minute video presentation of the DAHP program. The video explains the three health plan options, important components of a managed care system, such as primary care, appropriate use of the emergency room and the importance of preventive health and services. After the video, recipients meet privately with an enrollment interviewer where questions can be answered about the health plans and primary care provider selections can be made.

The Key Roles of Dayton Area Health Plan

DAHP is the umbrella organization for the mandatory enrollment program. All enrollment data is maintained and updated by DAHP. The capitation payment for all enrolled ADC recipients is paid to DAHP, and, after applying an age/sex adjustment and other factors, payment is passed through to the participating health plans.

DAHP also has a coordinating and monitoring role. Cost and utilization data for all three plans are monitored and analyzed with an emphasis on identifying trends and program-wide deviations and problems. In this way common solutions can be applied. This approach is not only beneficial to both members and providers, but holds the best hope for a positive impact on the health status of ADC recipients. Furthermore, health education programs can be designed exclusively to meet the special needs as identified by a county-wide monitoring system.

Operation of the Health Plan Network

The second function of DAHP is operation of the Health Plan Network. While the HPN functions much like a traditional HMO, its mission is different from the typical HMO plan.

The HPN was established as a contracting mechanism for independent community Medicaid providers, which in turn gives ADC recipients expanded (provider) choices. After payment of management fees, all funds are designed to flow through to providers thus maximizing reimbursement to participating providers, and to the extent possible - distributing surplus revenue.

Provider Participation

With the HPN, ADC recipients are afforded an additional level of choice. Participating providers in the HPN include 360 private practice physicians; 142 primary care providers, (123 independent practice physicians and 19 primary care delivery sites - mainly hospital based clinics and neighborhood health centers), 245 physician specialists and over 350 allied health care providers (pharmacies, dentists, optometrists, psychologists, etc.). All eight Montgomery County hospitals have contracted with the HPN to provide inpatient, outpatient and emergency room services.

With the exception of the hospital based clinics and neighborhood health centers, who are paid a monthly primary care capitation, all other providers are reimbursed on the prevailing Ohio Medicaid Fee Schedule.

As an incentive for participation, physicians receive an additional five percent reimbursement; however, this amount is withheld until year-end when utilization targets can be examined - at which point the stated goal is to return this withheld amount to physicians. Inpatient hospital services are reimbursed on the Ohio Diagnostic Related Grouping (DRG) rate system.

The key components for provider acceptance and satisfaction under the HPN, is minimal change with flexible billing procedures and faster payment turnaround. HPN has experienced a high degree of provider acceptance and satisfaction by minimizing Medicaid program policy deviations and instilling flexibility to provider payment issues.

Provider billing is accepted on all common billing forms, and can be computer generated by magnetic tape. Provider payment is made on a two-week to 30-day basis for those billings with no associated problems (i.e. pended for a referral, duplicate billing). Furthermore, for services requiring prior authorization, response is expedited by phone or within a one-week turn-around. (These requests previously had to be submitted to ODHS, often taking up to six weeks for a response).

HPN providers have responded enthusiastically to the benefits of a locally administered program. Part of this response is due to the support given by a Provider Relations department which is dedicated to servicing provider needs in the areas of training and office staff orientation, and expedited problem resolution.

2. A recent provider survey revealed that 80% of the providers felt that eligibility information was more readily accessible and the local administration was more effective than a state-wide program.

3. The DAHP project was conceived as an innovative program to bring the health care services for the needy to the same level as those private pay and insured citizens. This has been accomplished!

Additionally, DAHP has reduced public spending through an efficient management system and will produce an annualized savings of over $3.5 million.

4. Section 1903(m)(2)(A)(ii) (the "enrollment mix requirement") of the Social Security Act (42 U.S.C. Section 1396b) provides that a health maintenance organization (HMO) or a health insuring organization (HIO), in order to qualify for State-administered Federal funding, must meet the requirement that no more than 75 percent of the membership of the entity enrolled on a prepaid basis may consist of individuals who are eligible for benefits under Medicaid, Medicare, or both.

In other words, at least 25 percent of the prepaid membership must be composed of people who are not eligible for benefits under either Medicaid or Medicare.

It is clear to the community leaders in Dayton, Ohio that DAHP is fulfilling it's charge - without entering the commercial marketplace. It has never been the intent of those involved in the program to create a "new" company to enter the competitive world of health insurance.

In order to exempt DAHP from meeting the 75/25 mix, specific action by Congress is necessary.

I believe DAHP has proven itself; I believe DAHP has been a benefit to those on public assistance in the 3rd Congressional District, and I respectfully ask that you act favorably on this exemption request.

III. FEDERAL WAIVERS AND LEGISLATIVE REVIEW

As the DAHP Program began its development phase in early 1986 there were two major hurdles to overcome in order to bring the program to an operational status. Federal Waivers had to be received in order to operate a mandatory enrollment program. A second hurdle was a review by a (State) Legislative Oversight Committee.

Federal Waiver

In order to implement a mandatory, lock-in program, the Ohio Department of Human Services submitted a waiver application to HCFA in June, 1986. Specifically, the following program waivers under Sections 1915(b)(1) and (2) of the Social Security Act were requested and subsequently approved in August, 1989:

- Section 1902 (a) (1) - State-wideness
- Section 1902 (a) (23) - Freedom of Choice
- Section 1902 (a) (10) - Comparability of Services
- Section 1902 (a) (30) - Upper Payment Limit Requirements of the Social Security Act

The Federal Waiver was approved for a two-year period and was contingent upon an independent evaluation of the DAHP program with special emphasis on cost effectiveness, recipient access to care of adequate quality and the program's consistency with the objectives of the Medicaid program.

A separate enrollment mix composition waiver under Section 1903 (m)(2)(A)(ii) was submitted to the (Chicago) HCFA Regional office in July, 1988 and approved effective with implementation of the DAHP program (May 1, 1989).

In keeping with the philosophy of DAHP, the enrollment mix requirement will be met by the County General Assistance program recipients who will be enrolled under the DAHP operated Health Plan Network.

Legislative Review

Following a series of legislative hearings on Ohio's Medicaid HMO Program in early 1986, ODHS made a public commitment that it would not initiate any mandatory enrollment programs until such time as a legislative oversight committee was formed to review such proposals.

While awaiting the federal review of DAHP's waiver application, ODHS approached the Ohio Senate Subcommittee on Medicaid HMOs and requested that it perform a limited interim legislative oversight function with respect to the ongoing development and implementation of the DAHP program.

The subcommittee agreed to take on a limited oversight role and contracted with an out-of-state consultant to complete a study of the DAHP program.

The subcommittee held a public hearing on the DAHP program in Dayton in late 1986, and one in Columbus in early 1987. During the first half of 1987 DAHP met with community representatives to further analyze and discuss the program. Overall however, community support for DAHP remained as strong as when the need for such a program was first voiced in 1983. In August, 1987 Ohio Governor Richard Celeste publically reiterated his support for the DAHP program.

A third and final hearing on DAHP was held in September, 1987 and the legislative subcommittee completed its review with a formal statement which concluded that the committee had completed its legislative charge and that based on public testimony and research, there was no reason why the DAHP program should not move forward.

RATIONALE - WHY DAYTON AREA HEALTH PLAN SHOULD BE GRANTED AN EXEMPTION TO THE ENROLLMENT MIX REQUIREMENT

1. Dayton Area Health Plan is licensed and regulated as an HMO.

   In addition to being structured as an HIO, DAHP became licensed as an HMO in the State of Ohio. HMO licensure was sought after the COBRA provision (1986) which stipulated that HIOs meet the same requirements as HMOs (namely, enrollment mix requirement).

   As a licensed HMO, DAHP is regulated by the Ohio Department of Insurance and the Ohio Department of Health. Financial solvency and quality assurance areas are monitored by these two State regulatory agencies. Additionally, the DAHP program is monitored by the Ohio Department of Human Services by virtue of the risk contract between the parties.

   Unlike most other licensed Ohio HMOs, DAHP was required to post $300,000 in reserves before licensure was granted by Ohio Department of Insurance in June, 1986. Further, the continuing financial viability of DAHP will be closely monitored by the Ohio Department of Insurance.

2. The Dayton Area Health Plan Program does not impair access to or quality of care.

   Access to care: Although enrollment under the DAHP program is mandatory, recipients can choose any of the participating providers (as their Primary Care Manager) and participation is open to all providers. Further, a substantial majority of providers in Montgomery County do participate in the program and incentives for provider participation are offered in the form of increased physician fees in excess of normal fee-for-service rates.

   A primary goal of DAHP has been to expand provider choices available to ADC recipients.

The benefits of a locally administered program, particularly in the areas of faster reimbursement, simplified claims processing, and a Provider Relations department dedicated to servicing provider needs, have been tantamount to achieving the goal of an expanded provider base.

A Provider Council was appointed by the DAHP Board of Trustees as a means of assuring direct provider feedback and input into policy making. The twenty-two member Provider Council represents every provider area and has had an active voice in setting direction and policy for the program. Further, this process has, for the first time, given providers a voice in how the Medicaid program will be administered in a localized area.

As a health insuring organization, community providers that have heretofore provided Medicaid services can continue their participation under the **Health Plan Network**. Reimbursement mechanisms and policies are very similar to the traditional fee-for-service system although significantly improved through local administration. Providers who have had limited Medicaid practices (i.e. 25 patients) may also continue to participate. Providers who had stopped accepting Medicaid because of slow and cumbersome reimbursement, have been encouraged to participate in a locally administered program with speedier payment turnaround (15 to 30 days) and simplified claims submittal procedures. New providers, as well, have agreed to participate.

In order to have consumer input and feedback, during both the development and operational stages, the Board of Trustees formed a Consumer Council to accomplish this objective. Represented on the Consumer Council are community advocacy organizations such as the County Ombudsman, local neighborhood priority boards, the Community Action Agency and actual consumers. The Consumer Council has been active in reviewing the member grievance system, materials for members, and in bringing member issues and problems to the attention of the council. The Chairman of the Consumer Council has a seat on the DAHP Board of Trustees in addition to a second consumer Board seat.

Quality of Care: The Purpose of the enrollment mix requirement is to ensure that enrollees in a Medicaid HIO or HMO receive the same quality of care available to the general population.

In the traditional Medicaid fee-for-service system, there are few quality standards or safeguards. By nature of a prepaid contract with the Ohio Department of Human Services, HMOs are required to follow the Joint Commission on Accreditation of Health Care Organizations'adopted quality assurance guidelines, and to undergo an extensive annual quality assurance audit.

The Quality Assurance Program of DAHP is guided by a Quality Assurance Committee, and a Board-level Quality of Care Oversight Committee is actively involved in monitoring the access and quality issues of the DAHP program.

A substantial majority of providers in the community participate in the Health Plan Network and serve private pay patients as well. As an example, the highest volume private Medicaid physician practice in Montgomery County has approximately 50 percent non-Medicaid patients in the total patient load.

There are no private practice providers in the county who rely solely on Medicaid patients, and to the contrary - as just described, only half of the largest practice might be dedicated to Medicaid patients.

The major hospitals in Montgomery County have resident training programs and all participate as primary care delivery sites with one or more of the three health plans. A poignant factor in the development of DAHP was the political necessity of having all of the major Medicaid providers under contract.

DAHP therefore contends that Montgomery County ADC recipients have been mainstreamed into a community based health care delivery system that serves a total pupulation mix.

Further, many Medicaid HMO programs have, by design, limited provider panels for easier control and adaptation to a capitation system, only to find it difficult to obtain commercial enrollment because of the limited provider base. Clearly a larger and expanded provider panel is a major deciding factor for joining a managed care program.

3. A public sector managed care program can serve needs of future.

The philosophy behind the Dayton Area Health Plan program, as a vehicle for providing quality and cost effective health care to low income populations, positions it to serve the needs of other low income groups as well.

The Montgomery County General Assistance (GA) caseload will be enrolled into the DAHP operated Health Plan Network in early 1990. This public assistance group, who have heretofore been restricted to receiving health care from four county-operated neighborhood Health Centers, will have access to the over 700 DAHP network providers. Not only will provider access be greatly expanded, but local providers will once again gain access to serving these recipients.

Montgomery County will soon participate as a State sponsored demonstration site for serving uninsured groups. DAHP is viewed as a potential structure for delivering health care services to the uninsured demonstration participants. After a two-year demonstration period, ending with a formal evaluation of the various approaches, a permanent State-wide model is envisioned similar to what other states are implementing (i.e. State of Washington).

As Ohio implements welfare reform measures, namely expanded Medicaid eligibility for employed ADC recipients, the DAHP model once again will serve the needs of this important recipient segment. The experience and adaptation in a public DAHP managed care system will ready employed individuals to traditional commercial insurance products - HMOs, PPOs, TPAs, etc.

TESTIMONY OF

THE AMERICAN PSYCHOLOGICAL ASSOCIATION

THE MENTAL HEALTH LAW PROJECT

THE NATIONAL ALLIANCE FOR THE MENTALLY ILL

THE NATIONAL ASSOCIATION OF AREA AGENCIES ON AGING

THE NATIONAL ASSOCIATION OF DEVELOPMENTAL DISABILITIES COUNCILS

THE NATIONAL COUNCIL OF COMMUNITY MENTAL HEALTH CENTERS

THE NATIONAL MENTAL HEALTH ASSOCIATION

This testimony reflects the general position of the following organizations, which may also submit separate statements addressing additional issues.

American Psychological Association
Mental Health Law Project
National Alliance for the Mentally Ill
National Association of Area Agencies on Aging
National Association of Developmental Disabilities Councils
National Council of Community Mental Health Centers
National Mental Health Association

The aforementioned organizations wish to commend the Chairman for his leadership in the ongoing effort to provide services for the elderly and disabled in need of long-term care and for his continuing work to ensure that the Medicaid Program fulfills its mandate to meet the health care needs of poor Americans.

H.R. 3933, which would give State Medicaid programs the option of providing home and community-based services is an important first step towards the goal of long-term care for all who need it. Most importantly, it alters the current reimbursement bias favoring institutional long-term care. For these reasons, we strongly support the bill. However, we have several concerns about the bill's use of disease-specific eligibility criteria, not the least of which is the precedent it sets for future long-term care legislation.

Another major concern relates to the pressing need for home and community-based services for persons who are functionally disabled by mental conditions or disorders. If OBRA '87 is implemented as written and intended, then persons who are functionally disabled by mental illness but who do not require the level of care provided in nursing homes will have to rely on home and community-based services for their long-term care needs. In light of the OBRA '87 provisions, it is all the more important to ensure that the eligibility criteria used in long-term care proposals appropriately measure disability among persons with mental impairments. Additionally, the appropriate criteria should apply to all persons with mental disorders.

Our major concerns are:

1. Eligibility for Long-Term Care Services Should be Based on Functional Disability

There are many diseases, conditions, disorders, and impairments--both physical and mental--which may cause functional disability. The cause of the functional disability is relevant when determining appropriate treatment and service needs. For example, among the elderly, symptoms of both dementia and affective disorders may be caused by physical conditions and are potentially reversible with treatment. Similarly, persons who are functionally impaired by clinical depression or other serious mental illness may be able to function independently once treatment is initiated. However, once it is determined that a physical or mental impairment is chronic or irreversible, then functional disability should be the focus of determining both the need for long-term care and the type of services required. However, H.R. 3933 subsection "(c)"(B) specifies that the determination of functional disability not only be based on measures of functional impairment (as determined by the ability to perform activities of daily living or the need for protective supervision) but that the functional impairment must result from a primary or secondary diagnosis of Alzheimer's disease.

2. Functional Disability Should be Determined by Appropriate Measures of Functional Impairment

In order to equitably determine eligibility for long-term care services, it is necessary to have meaningful indicators of functional disability. Because the majority of those 65 and older have one or more chronic health conditions (86%), the presence or absence of a disease, or of a physical or mental impairment, is generally not considered a useful measure to determine the need for long-term care services. Similarly, specific medical diagnoses, by themselves, are not always useful in determining functional status. Rather, the assessment of the need for long-term care services should focus on the ability to function independently. The measure used to determine functional disability in H.R. 3933 subsection (c)(A), i.e. the ability to perform 2 out of 3 activities of daily living without assistance, is most appropriate for persons with physical impairments, and for some persons with mental impairments. It is also appropriate for targetting services to persons with the most severe disabilites.

Much of the research in the area of disability determination among the elderly has used some measure of activities of daily living (ADLs) to assess functional impairment. This research indicates that the ADL scale is sensitive to changes in functional status, and as such, is predictive of the need for long-term care services. The ADL scale can adequately measure functional impairment resulting from both physical and mental conditions. However, there are many instances when the need for physical assistance to perform ADLs will not adequately measure a person's ability to function independently. For example, individuals impaired by mental disorders may be able to perform ADLs, but may need cueing or supervision to do so safely and consistently. For this reason, additional measures are needed and are included in H.R. 3933. The measures used to determine functional disability in subsection "(c)"(B) are appropriate for a wide range of mental impairments, however, the bill limits their application solely to persons with a primary or secondary diagnosis of Alzheimer's disease. Equitable treatment of persons with severe disabilities requires that these measures be used to assess functional disability and eligibility for long-term care services for all persons with mental impairments, not just those with a diagnosis of Alzheimer's disease.

3. Eligibility for Benefits Based on the Diagnosis of a Person with a Severe Disability Sets a Precedent with Potentially Negative Consequences

One of the goals of H.R. 3933 is to correct Medicaid's current bias towards institutional care in the provision of long-term care services. This bias is created by reimbursement policies which provide an economic incentive for patients to utilize institutional care. There is little reason to expect that eligibility for a benefit based on a diagnosis will not have a similar effect and lead to a recorded higher incidence of that diagnosis. This is particularly likely in the case of Alzheimer's disease which cannot be definitively diagnosed until after death.

Research on the impact of Medicare's Prospective Payment System (PPS) on the diagnostic case mix of psychiatric inpatient care in short-term non-federal general hospitals has shown a massive shift in diagnostic categories between 1980 and 1985 to a Diagnosis-Related Group (DRG) which allows a longer length of stay and consequently a larger payment to the hospital. The largest increase was in DRG 430 (the group including affective disorders) which more than doubled in frequency, and a concomitant decrease in DRG 426 (the group including depressive neurosis). The disorders included in DRG 430 are regarded by clinicians as very serious disorders.

If economic incentives can lead to increases in recorded diagnoses which are more serious and potentially stigmatizing, i.e. a psychosis rather than a neurosis, it is reasonable to expect that requiring a diagnosis of Alzheimer's disease for access to a much needed and highly valued benefit will result in an increase in recorded diagnoses of Alzheimer's disease. The implications of such an economic incentive are particularly troubling given that Alzheimer's disease is considered to be an irreversible condition. If this incentive was pervasive in both public and private reimbursement systems, it is possible that Alzheimer's disease could become the "preferred diagnosis", with many persons who have symptoms similar to Alzheimer's but with potentially reversible underlying conditions going untreated.

Another major concern about the precedential effect of disease-specific eligibility criteria is its potential negative impact on subsequent public long-term care proposals and on the development of private LTC insurance for elderly persons who are functionally disabled by mental impairments other than those caused by Alzheimer's disease. There have been several bills introduced in the past two Congresses which have sought to promote private insurance as a solution to the long-term care crisis. While there are many concerns regarding the ability of the private sector to meet the long-term care needs of the majority of the U.S. population, our particular concern relates to policy restrictions and underwriting practices which may exclude persons from coverage even if they can afford to purchase insurance.

The adoption of disease-specific eligibility criteria for long-term care under Medicaid would be a salient precedent which could undermine efforts to ensure that private long-term care insurance policies not exclude patients with mental disorders.

Cost Concerns

It is our understanding that the restrictive eligibility criteria in H.R. 3933 is due solely to cost concerns. However, we believe that including coverage for persons who are functionally disabled by mental impairments other than those caused by Alzheimer's disease will not significantly increase the cost of the bill.

Existing data suggest that, compared to the population that is functionally disabled by physical and cognitive disorders, the elderly population functionally impaired by other mental disorders is relatively small. Analysis of data from the 1984 Long-Term Care Survey and the National Medical Expenditure Survey by the DHHS Agency for Health Care Policy and Research indicates that only a very small proportion of the functionally disabled elderly--less than one percent--are disabled solely due to mental illness. The definition of functional disability used to obtain this estimate was quite broad, including both ADL and IADL measures.

Information from the Canadian long-term care system also points to the relatively small number of persons who are functionally impaired due solely to mental disorders other than the dementias. In British Columbia, a province with a population of approximately 3 million, the long-term care system serves the needs of all individuals who are functionally impaired, regardless of age or the cause of impairment. Out of approximately 25,000 elderly receiving services in long-term care facilities, an estimated four percent are functionally impaired solely by non-cognitive mental disorders. About half of these individuals are cared for in the Residential Mental Health Program, and the remainder are in long-term care nursing facilities.

Given this data, deleting the requirement of a primary or secondary diagnosis of Alzheimer's disease from the eligibility requirements should not significantly increase the cost of the bill. Should it result in a small increase, it would be more equitable to reduce the cost of the bill by increasing the severity criteria rather than excluding persons with functional disabilities in need of long-term care because they do not have a specific diagnosis.

Recommendations

We strongly urge the Subcommittee to address the needs of all severely functionally disabled persons. We are greatly concerned that the differential treatment of mental disorders in current public and private insurance coverage not be carried over into long-term care proposals. This differential coverage contributes to the prevalence of functional disability among persons with mental disorders since many could function independently if they received adequate treatment. For the population who, despite treatment, are functionally disabled by non-cognitive mental disorders, there is ample evidence, from programs in this country and in Canada, that the long-term care needs of this population are equivalent to those of the population disabled by physical and cognitive conditions and can be met by appropriately designed programs.

We recommend that H.R. 3933 subsection "(c)"(B) be changed to read:

"(c) Determination of Functional Disability.—

"(1) IN GENERAL.—In this section, an individual is 'functionally disabled' if the individual—

"(A) is unable to perform without substantial assistance from another individual at least 2 of the following 3 activities of daily living: toileting, transferring, and eating; or

"(B) has a cognitive or other mental impairment and is (i) unable to perform without substantial human assistance (including verbal reminding or physical cueing) or supervision at least 2 of the following 5 activities of daily living: bathing, dressing, toileting, transferring, and eating, or (ii) requires substantial supervision from another individual because the individual engages in inappropriate behaviors that pose serious health or safety hazards to himself or herself or others."

We thank you for this opportunity to present our views

MEDICAID BUDGET INITIATIVES

FRIDAY, SEPTEMBER 14, 1990

House of Representatives,
Committee on Energy and Commerce,
Subcommittee on Health and the Environment,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:45 a.m. in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. Waxman. Good morning.

The subcommittee will come to order.

This morning, the subcommittee begins the second of 2 days of hearings on Medicaid budget initiatives. The purpose of these hearings is to prepare the subcommittee to respond to whatever directives are issued to the Energy and Commerce Committee under the terms of the agreement reached at the budget summit now in progress.

On Monday, we focused on Medicaid initiatives to reduce infant mortality and to improve child health. Unfortunately, we heard the States testify against the initiative to reduce infant mortality and to improve child health.

We also heard the administration testify against these same initiatives, both of which would implement campaign promises made by President Bush 2 years ago. We also looked on Monday at initiatives to make home and community-based services available to frail, elderly and disabled people, and to make early intervention services available to persons with HIV infection. Again, the administration made clear its opposition to each of these initiatives.

We heard a good deal about what the Bush administration is against, but not much about what it is for. The administration is developing a managed care initiative, but it does not have any concrete legislative proposal for us to consider on this or any other Medicaid issue.

This morning's hearing will examine a range of Medicaid initiatives to the subcommittee, reform of the purchase of prescription drugs, coverage of substance abuse treatment services and the creation of a new Medicaid-eligible category for individuals insured under private, long-term care policies.

Even though the administration has not yet introduced an administration's care proposal, the subcommittee will hear this morning about quality and program integrity issues in Medicaid managed care arrangements.

Before calling our first witness, I would like to recognize members of the subcommittee for opening statements and to call on Mr. Bliley first.

Mr. Bliley. I have no statement.

Mr. Waxman. Mr. Wyden.

Mr. Wyden. Thank you. I want to commend you for all the tremendous work that you have done over the years going to bat for those on Medicaid.

Today the subcommittee will focus special attention on the issue of prescription drug prices in the Medicaid program. My colleague and fellow committee member, Jim Cooper, and I have introduced legislation, H.R. 5589, the Medicaid Prescription Drug Fair Access and Pricing Act, to bring a dose of free enterprise and true competition to the way Government purchases medicine.

This version of the legislation is substantially different from earlier versions of the legislation. There is no therapeutic substitution, so a doctor can still direct that a specific drug be prescribed. There is no therapeutic equivalence committee, so there is nobody making decisions about which drugs are preferred.

I am particularly pleased that Senator Pryor is here, the Chair of the Senate Aging Committee, whose leadership, in my view, and groundbreaking investigation gave a great impetus to this effort to end blatant price discrimination.

In my view, Senator Pryor is doing a tremendous job as the chairman of the Senate Aging Committee. It has been a pleasure to work with him on a variety of issues over the years. Senator Pryor has been the spark plug in terms of blowing the whistle on this issue.

It is a pleasure to have him here.

The Nation's health care program for the poor is being taken to the cleaners. Large nonprofit private purchasers and even other Government programs—such as the Department of Veteran's Affairs—pay on the average 40 to 70 percent less than Medicaid for prescription drugs. With what the drug companies have overcharged Medicaid during the last decade alone, millions of poor families could have received basic health benefits.

Medicaid represents 12 to 15 percent of the market, and it spends over $3.5 billion annually for drugs. And no one would dispute that Medicaid is the ultimate nonprofit health care program. So why isn't Medicaid getting competitive discounts for drugs?

The simple answer is that the drug industry has been stiffing the Medicaid program. If you are a preferred customer in the private sector, they will negotiate with you and you can hold the prices down. When it comes to Medicaid, the Government has just handed over a blank check to the drug industry and said "you fill in the numbers."

This country cannot afford to let the drug companies gobble up scarce Government dollars. Every budget cycle, low income people, doctors, and hospitals, are asked to make a big contribution towards meeting the Gramm-Rudman target. It is time we made drug companies contribute, too.

The drug companies who are testifying today will make three arguments in opposition to H.R. 5589, the legislation that Senator Pryor and myself and Congressman Cooper have introduced.

First, the drug industry is going to argue that our legislation is basically price controls. That is just inaccurate.

How is it price controls to let Medicaid negotiate with the drug companies for the best price the way the local big HMO does?

Second, the drug companies are going to say that this legislation will discourage them from investing in research and development on new drugs. Once again, they are wrong. The Federal Government already provides general tax credits for the sole purpose of encouraging drug R&D.

I am one of the Democrats who plans to support the President's tax oriented growth proposals in this area.

They will say this results in second class medicine for the poor.

The real damage to low income health care is done because Government dollars that could be used to serve low income people are being skimmed off by the companies.

No savvy cost-conscious private purchaser of prescription drugs would pay the prices that Medicaid does on a daily basis. There are extraordinary examples.

Feldene of Pfizer, Medicaid pays $1.68; VA pays 87 cents; difference: 93 percent.

Zantac of Glaxo, Medicaid pays $1.18; VA pays 79 cents; difference: 49 percent.

Seldane of Marion-Merrell Dow, Medicaid pays 61 cents; VA pays 40 cents; difference: 53 percent.

Inderal of Wyeth-Ayerst, Medicaid pays 40 cents; VA pays 6 cents; difference 566 percent.

The list goes on and on and is well documented in the charts. I think the Congressional Budget Office estimates are going to show that the legislation that has been introduced would save the Federal Government about $2.5 billion over 5 years and to put it in perspective, $2.5 billion could provide full Medicaid benefits for half-a-million children each year.

It would provide pre- and postnatal care to 100,000 poor pregnant women. It could fund initiatives to provide home care to the frail elderly, community care for the mentally retarded, cover all pregnant women and infants up to 185 percent of poverty, and phasein coverage for all children in families below 100 percent of the Federal poverty level.

Last, Mr. Chairman, I think that the company's proposals are certainly helpful and they are a step in the right direction. But they are no substitute for the legislation.

I think we also ought to understand what is the motivation behind these proposals. The motivation is that these companies know that Congress is finally looking at cutting off the gravy train. It is high time.

I look forward to hearing from our witnesses.

I appreciate the chance to make this statement.

Mr. Waxman. Thank you, Mr. Wyden.

We have other members of the subcommittee who wish to make opening statements. Ordinarily, we would call no them at this point, but I understand the Senator has a vote on the Senate floor. So we will ask the members to withhold their opening statements so we can hear from the Senator now.

Senator, I think Mr. Wyden expressed the views of all of us on this committee. We owe you a tremendous debt of gratitude in this and so many areas that affect the health of the elderly in this country. Your full text of your statement will be in the record.

We will ask you to proceed with your oral statement.

STATEMENT OF HON. DAVID PRYOR, A U.S. SENATOR FROM THE STATE OF ARKANSAS

Senator **Pryor**. Mr. Chairman, and members of the committee, let me thank you for allowing me to come.

We do have a vote at 10:15. It may be a vote that I may miss. I think this is more important.

But I do appreciate the opportunity to comment. No one in the Congress, Mr. Chairman, knows more than you do and the members of this committee about the sad state of our Medicaid programs. Our State-administered programs for the poor are underfunded, overburdened.

As a result, too many desperate needs of our Nation's poor go unmet. What is more, any possibility of Federal assistance to the States today is being held hostage to an everincreasing deficit. Being held hostage, I think, also describes what the drug companies of our country are doing to our $8 billion Medicaid prescription drug program. This Federal-State financed system is being forced to pay as much as 40 to 60 and 70 percent more for the same drugs purchased by hospitals, HMO's and our own Veteran's Administration.

By not having access to these discounts, the Medicaid program has shouldered the unyielding and entire weight of prescription drug price inflation. We all know this is no light burden.

In fact, as the chart which I brought this morning demonstrates, consumer prices over 10 years have increased 58 percent while prescription drug prices have increased 152 percent.

Mr. Chairman, when I decided to take on this issue, I was under no illusion that it was going to be an easy fight. The PMA, Pharmaceutical Manufacturers Association, and their members have waged a constant and a vigilant war on my proposals. Frankly, I sometimes wonder if it might not cost the pharmaceutical manufacturers less money to sign off on these very simple proposals than to pay their many lobbyists and public relations firms who have been hired to defeat it.

Yet, in spite of the intense and expensive campaigns against these efforts, I believe that the Congress is on the verge of enacting legislation that addresses the inequities that we have spotlighted. Why do I say that?

It is very simple: it is because there is no logical reason why the Medicaid program, one of the largest purchasers of drugs in the country should be denied access to these same discounts, especially if these particular drugs are to serve the poorest of the poor in our society.

Mr. Chairman, the drug manufacturers have forced Medicaid to swallow this double dose of bitter medicine for too long. I hope we can look at several examples of discounts that the drug manufacturers offer to other purchasers like Federal Government agencies. Let's compare these discounted prices to Medicaid prices.

You will be hearing from representatives of Glaxo. Glaxo has an incredibly effective antiulcer medication, zantac. Federal Government purchasers like Veteran's Administration pays 79 cents a tablet. Medicaid pays $1.18 per tablet, almost 50 percent more.

Upjohn offers motrin—it is a popular antiarthritis drug—to the Federal Government, $6 for a bottle of 100 tablets. Medicaid pays $16 for the same bottle, the same number of tablets. That is 2.5 times the price.

Pfizer sells Feldine, a very expensive antiarthritis drug. They sell to the Federal Government 87 cents per capsule. Medicaid, $1.68 for each capsule, twice as much.

Making rough calculations, if Medicaid received just a fraction of the discount that the drug manufacturers offer to others, 20 to 30 percent in Medicaid, we could save $200, $300 or $400 million a year.

There is simply no justifiable reason why Medicaid should not have access to these discounts. The manufacturers have an excuse. They say why each plan that we introduce will not work. They tried to defeat the original bill, S. 2605, by claiming it would provide second class treatment for our Nation's poor.

Clearly, Mr. Chairman, and I say this as sincerely as I can, there is nothing further from the truth. They know it. I know it, and I hope and pray you know it.

S. 2605 utilizes the same state-of-the-art negotiating system in place in hospitals and HMO's around this country. It requires States to cover all FDA-approved drugs. It would save $1.6 billion over 5 years.

This is not second class treatment. What is second class treatment is when the drug manufacturers practice the art of charging our Nation's most exorbitant prices for a commodity that is so essential to the very life of so many American citizens. Today you know, and I know, in town meetings, the elderly poor stand up and say today they are having to make a choice of the drugs that have been prescribed to them by their physicians and the drugs that they can afford to pay.

The manufacturers have candidly admitted recently that they are very concerned that other third party insurers will also want to negotiate better pricing by using the competitive bidding process.

The system in S. 2605 is based on a time-tested competitive practices system hospitals and HMO's use every day. They are using it today to buy drugs and obtain a fair deal for those who need the drugs.

Some manufacturers are so concerned about the long-term impact of S. 2605 that they shocked the world recently by offering their own proposals for Medicaid drug savings. I appreciate this initiative. I appreciate this sensitivity, but there is one basic problem with all the plans.

They do not achieve the savings that Medicaid needs and deserves. Under their plans, drug manufacturers could reduce or eliminate their proposed discounts at a moment's notice.

That is like putting the fox in charge of the hen house. Unfortunately, the past actions of the drug manufacturers of this country do not leave me with any confidence.

I wish I could say otherwise. However, we need only look at how the drug manufacturers tried to renege on their voluntary promise to give rebates to the Women, Infants and Children's Program, the WIC Program, for infant formula. The pharmaceutical manufacturers, Mr. Chairman, of this country, claim that the drug companies are entering into agreements right now without Federal legislation because of so-called "market forces". The truth is that the drug companies' sudden change of heart has been the result of one thing, that is Federal legislation that is now introduced in the House, now introduced in the Senate.

It will take Federal legislation to insure that these companies do their fair share, that Medicaid receives the discounts it deserves. On Wednesday, Mr. Chairman, I introduced the Medicaid Antidiscriminatory Drug Price and Patient Benefit Restoration Act.

I was pleased Congressman Wyden and Congressman Cooper introduced similar legislation here in the House. These bills require all drug manufacturers to provide Medicaid with the same discounts they provide other purchasers.

If the manufacturer does not offer the best price, then that manufacturer will be denied access to the Medicaid market. I have a summary of that bill I would appreciate having included in the record.

In conclusion, I am very confident that both plans that we have developed together will result in substantial cost savings to the Medicaid program. It is important now for this Congress to remain on track, not to be distracted, not to be misinformed, not to receive misinformation and have truths concocted by an industry that for too long has gotten away with a legalized form of robbing the poor in the United States of America.

This is an era of extraordinary budget constraints. Savings from entitlement programs may be the only way to achieve the realistic deficit reduction practice.

We simply cannot reduce Medicaid payments to physicians and pharmacists to cut Medicaid drug benefits while drug manufacturers continue to profit from an unreasonable pricing scheme.

Today is the time for the drug industry to do its fair share. It is now time for the Federal Government to force them to act and only through Federal legislation will these companies act and act in a responsible way.

Let me say it is not the fault of that local pharmacist out there that every day has to stand behind that counter and tell you and me and our kinfolks that their drugs have gone up once again. They are not a part of this scheme.

In fact, Mr. Chairman, we might just see this additional chart: in the last year, in 1988, the pharmacists made basically 3 percent profit where there was a 15 percent profitability for the drug companies.

We might look at what came from Forbes Magazine April 1990, on the most profitable of all industries in the United States. Look at the yellow graph line, Mr. Chairman, of the Median Fortune 500 companies, they are way down there. The blue line, the second highest profitable industries. The red line, guess who, the most profitable of the industries in the country, the pharmaceutical manufacturers.

We have seen the chart with the 152 percent inflation rate. What you may not have seen is a local series of ads that have been run across the country by the pharmaceutical manufacturers. I have gathered these. They are available for your use. They are attempting to influence the American public on how much these firms spend for research and development.

The truth of the matter is that when they spend research dollars, when they spend development dollars, what do we do? We give them a tax break. They write it off.

We give them FDA protection. We give them a patent protection from the U.S. Patent Office.

Most of the time then they go to Puerto Rico to manufacturer the drugs where they pay absolutely no State or Federal income taxes from their operations there. From every end of the spectrum, Mr. Chairman, the drug manufacturers have abused and taken advantage of a system.

There is only one way that we can stop it. That is in Federal legislation.

If you or this committee have suggestions to make about either of the proposals that I have introduced, I am open, I am willing to listen to change, but whatever the case may be, let's do something, Mr. Chairman, and let's do it now.

Thank you very much.

Mr. WAXMAN. Thank you, Senator Pryor.

You have a reputation as the chairman of the Special Committee on Aging and as a member of the Senate Finance Committee of trying to make these Government programs more effective and improve their working operation. I think you have outdone yourself.

By introducing S. 2605 last May, you set in motion a remarkable series of events that have brought concessions already from an industry that does not usually show much flexibility.

It is not hard to understand why you are unopposed to reelection this November. I want to commend you and express my enormous respect for you and admiration for the leadership you have given to this issue.

Senator PRYOR. If I may respond to the issue of not being opposed for reelection. I was asked that recently.

One year ago in Leningrad they had the first public elections in 50 or 60 years. The mayor of Leningrad was unopposed and he was defeated for reelection.

Mr. WAXMAN. I trust that would not happen to you. I want to thank you for your testimony.

Mr. Wyden.

Mr. WYDEN. I think the fact that we have the opportunity to work on the second bill shows that you have walked the extra mile to be reasonable. There are a number of concerns expressed about the first one.

You and a group of us reached out to make these changes. I think just the fact that you take the second opportunity indicates just about as great a statement as you can make about being reasonable and wanting to work with people. I commend you for it.

Senator **Pryor**. Thank you very much.

Mr. **Waxman**. Thank you, Senator.

We are pleased to have our colleague from the full Energy and Commerce Committee, a strong advocate for rural health and efficiency in Government programs, with us to testify. Congressman Cooper on Monday introduced H.R. 4181 with Congressman Wyden, the Medicaid State Share Protection amendment.

He is here to further discuss the Medicaid Prescription Drug Fair Access and Pricing Act of 1990.

STATEMENT OF HON. JIM COOPER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mr. **Cooper**. Thank you. Sometimes an idea comes along that is so simple, so powerful, and so compelling that people wonder why it hadn't been considered years before. Our colleague in the other body, Senator Pryor, has come up with such an idea, and my House colleague Ron Wyden and I are introducing legislation today in the House to implement that idea.

The idea is simple. When the U.S. Government is a large purchaser of something, it should be able to negotiate to get either the lowest possible price, or at least as good a price as other bulk purchasers are getting. The U.S. Government should be run more like a business, which almost always bargains to get the best possible deal. The converse of that is the Government should never blindly pay the highest possible prices, thus wasting precious taxpayer dollars, because it forgets to ask for a discount.

In many cases, the U.S. Government does get reduced rates. When the Federal Government purchases everything from automobiles to fountain pens, even renting hotel rooms, a substantial discount is available from the supplier.

I think most Americans would be shocked to learn that the U.S. Government, through the Medicaid program, is the top purchaser of prescription drugs in America and yet rarely get the discounts that smaller purchasers get. In fact, we taxpayers usually end up paying top dollar. In most cases, Government hasn't even tried to get lower prices. We have let the drug companies tell us how much they would like to be paid, and we have paid them with no questions asked.

The cost of this extravagance has been largely hidden, but it has been extraordinary. This unlegislated, unrecorded subsidy to the pharmaceutical industry has cost the Nation's Medicaid program, and thus the Nation's taxpayers and poor, an estimated $2.5 billion over 5 years, according to the Congressional Budget Office and the Office of Management and Budget.

This vast amount of money has not reached the poor in America primarily because the Medicaid program did not get a better deal from U.S. drug companies.

This is not to say that the U.S. pharmaceutical industry is all bad. Far from it. It leads the world in innovation and quality.

Countless lives have been saved and improved as a result of the industry's research and product development. Being the world leader is not cheap. It takes money and lots of it.

But the drug companies have found one way of getting lots of money from the Federal Government without the need for an appropriation or even an explanation. By simply refusing to bargain with the Federal Government, they have created a secret subsidy for themselves that is unfair to the taxpayers and poor of America.

The U.S. pharmaceutical industry gives discounts to the vast majority of hospitals in America because they are smart enough to demand them. The industry also gives lower prices to the Veteran's Administration hospitals and to health maintenance organizations. Why not to their biggest customer, the U.S. Government's Medicaid program?

Some States have caught onto this game and have begun the bargaining process. But they have often been forced to resort to formularies, restrictive lists of drugs that Medicaid patients may be prescribed, in order to gain a bargaining advantage with the drug companies.

The Federal Government has the power and the responsibility to make sure that every State, every taxpayer, and every poor person, is protected from wasteful spending in the Medicaid program. The Pryor bill, which we are introducing today, achieves these savings without harming the legitimate interests of either poor citizens or drug companies.

This bill should be distinguished from an earlier bill, S. 2605, which Senator Pryor introduced on the same subject but with a significantly different set of solutions.

This bill we are introducing today assures access to the best prescription drugs on the market for our Nation's poor. No one need fear the creation of a system of second class drugs for our Nation's poor.

In fact, the estimated budget savings of $2.5 billion over 5 years that this bill will produce should allow the Medicaid program to reach out to many more people in order to serve them better.

Major companies in the U.S. pharmaceutical industry itself have shown that they can live quite well when they give discounts to their largest customer. Several leading drug manufacturers have offered voluntarily to treat the U.S. Government as they do their other large customers, instead of discriminating against it. Unfortunately, these voluntary industry initiatives, while commendable, do not go far enough and lack adequate safeguards. To be sure, the Pharmaceutical Manufacturers Association is still against the legislation, as you would expect a trade association to be. But I feel that it is losing more and more of its members on the issue. These companies expect discounts from their suppliers; the Federal Government expects discounts from its suppliers.

The leadership of the pharmaceutical industry will be tested by the manner in which it wages this fight. Will it continue to sink to the lowest common denominator and fight to the last breath of the last company that wants to preserve this hidden and unfair subsidy or will it be thankful for its many years the U.S. Government has paid top dollar and instead argue for open and efficient subsidies that it is prepared to defend in public and on the merits?

To be honest with you, the first skirmishes have not been encouraging.

A very common tactic has been used: discredit the first Pryor bill in the hopes that all subsequent legislation, such as the bill we are introducing today, will either not be noticed or discredited.

Another tactic: don't work with the Congress to improve the legislation and discourage those companies who are willing to; make Congress figure out everything on its own.

Efforts have even been made by the pharmaceutical industry to convince our Nation's poor that they are better served with the current system, in which our Nation's Medicaid program is hundreds of millions smaller than it could be if we did not secretly funnel that money to the pharmaceutical industry.

Efforts have also been made to hide the fact that so many of the new and expensive drugs being introduced today are so similar to existing drugs that they are little more than an excuse for a price increase. So much of our technological talent is being wasted on "me-too" drugs that cost a lot more but don't cure a lot more.

I would hope that this is an issue that businessmen in the pharmaceutical industry would treat as businessmen. Don't discriminate against your biggest customer, even if it is the Federal Government. Don't treat Uncle Sam like Uncle Sucker. Why? Because we all lose as taxpayers and as a Nation when we exploit our own Government.

I am not an enemy of the pharmaceutical industry. In fact, I have generally supported their initiatives. I am open to any argument they want to make for open, targeted subsidies to help it bring needed drugs to market. I am an enemy of waste, and of secret subsidies at the taxpayers' expense. The pharmaceutical industry of America needs to treat our taxpayers with more respect and offer them, and the poor of America, at least the discounts that they offer to other groups.

I would like to thank, again, this subcommittee, Congressman Waxman of California, and Ron Wyden of Oregon, for their present help and impetus behind this legislation.

Mr. WAXMAN. We want to thank you for that excellent statement.

While you are not a member of the subcommittee, I would like to invite you, if you have the time, to join us, although you may have other commitments for the day. This subcommittee wants to work with you.

I want to call on Congresswoman Collins for a statement at this point.

Mrs. COLLINS. Thank you, Mr. Chairman.

Let me associate myself with your earlier remarks commending our colleague, Mr. Cooper, for his eloquent statement which points out what this particular hearing is all about.

It is a pleasure to join with all of you today in receiving testimony on key initiatives which offer constructive approaches toward improving the Medicaid system. I look forward to an insightful, productive hearing.

While all of today's issues are of great interest, the question of reforming the Medicaid pharmaceutical reimbursement system is especially intriguing. I strongly commend Senator Pryor and my colleagues from our committee, Congressmen Cooper and Wyden, for their work in framing the debate on promising new solutions.

While Senator Pryor was speaking, I told Ron Wyden that it is such a great idea that I would cosponsor the bill right now because it makes good sense to do that for the kind of legislation that they have. That says, of course, that the amount being paid for Medicaid ought to be the least amount that anybody else is paying for it.

Their product, this legislation, respects the great effort which went into its construction. While it may be premature to embrace any single solution at this time, it is clear that we must take action in this area.

There are many inequities in the present system and I am very receptive to its improvement, for the sake of America's pharmacists, the Medicaid system as a whole, and especially the beneficiaries who must rely on it.

But most importantly, I am pleased to have Ms. Janet Shikles of the GAO here to testify on the report about the quality of care provided to Medicaid recipients by Chicago area HMO's, which her division recently completed at my request. It is a very revealing report that delves into the issue in great detail and uncovers problems endemic to the Medicaid system.

Although the GAO studied the practices of Chicago area HMO's, the results have nationwide implications. The GAO's comments concerning the Health Care Financing Administration are obviously not limited to Illinois. Also, in some cases, the practices of the Illinois Department of Public Aid, IDPA, may resemble practices elsewhere in the United States.

The results of the study are very disturbing to me. First of all, it is clear that the reimbursement system know as capitation, whereby Medicaid pays a fixed monthly amount per enrolled recipient to HMO's to provide all health services covered by the program, has a serious downside.

Although instituted to limit costs, it often has the practical effect of being an incentive to a health care provider to treat patients with less than adequate care, since the same reimbursement level is received regardless of the extent of treatment. Thus, the quality and quantity of care is often abridged.

Second, providers who subcontract with HMO's to provide Medicaid services to recipients are not obligated to adhere to the same risk-based contracting requirements as the prime contract HMO's. One notable area where this has been the case is in the requirement that no more than 75 percent of a provider's patients may be Medicaid and Medicare recipients.

In some cases, subcontractors have had over 90 percent of its patients tied to these programs. The result is that the provider is financially vulnerable.

This is one of many reasons why health care facilities become insolvent and are forced to close their doors. In the Chicago area alone, 14 facilities have been forced to shut down in the past 6 years, 5 of which were in my own Seventh Congressional District. All of the facilities' patients are the big losers in such a situation. Moreover, these closures have imposed even greater burdens on the surviving facilities.

Third, unlike Medicare, there is no minimum enrollment requirement under Medicaid. The need for such a requirement is to spread the financial risk of patient care over a sizable base, along the lines of basic insurance principles. While the large HMO's have enrollments well over 5,000—as Medicaid requires—over half of the subcontracting providers had less than 1,000 total enrollees, and six of them had less than 100.

Providers with such small Medicaid populations are, thus, much more vulnerable and exposed to financial insolvency. The residents and health care community of Chicago simply cannot afford to face another hospital closing.

Fourth, the actual quality of the service which is, in fact, provided to Chicago area Medicaid recipients is also questionable. The GAO report points out that the IDPA has not taken adequate action to ensure that the Chicago area HMO's develop effective quality assurance programs and it often has not pursued major questions of patient dissatisfaction.

For example, there was no followup to a survey which found that over 58,000 Medicaid recipients left their HMO over a 3-year period. Also, there was no followup to determine whether the scant records of preventative care is due to poor recordkeeping or a failure to provide these required services. The IDPA simply as not been doing its job effectively.

All in all, these findings point toward disaster. The problems are on many levels and the solutions must also be as well.

Some of the remedies are available to Congress. Consequently, I am in the process of preparing legislation, based on the GAO's findings, that take direct aim at some of the problems I have just described.

The GAO has been greatly helpful in isolating some of the principal contributors to the woes of the Medicaid program and we would be foolish to ignore these facts. I look forward to working closely with you, Mr. Chairman, and all of my colleagues in the upcoming weeks on both the problems identified and the solutions recommended by the GAO.

I appreciate the opportunity to discuss this fine report that Mrs. Shikles will discuss on the panel.

Thank you very much.

Mr. WAXMAN. Thank you very much.

Dr. Rowland, I would like to call on you.

Mr. ROWLAND. I have a couple of questions for my colleague, Jim Cooper.

I hear from many people about the high cost of prescription drugs. I want to commend my colleague for his efforts to hold down the cost of drugs, what they cost the Federal Government and for his efforts to reform the Medicaid program. In my own State of Georgia, there has been instituted a system, very similar, I understand, to what Senator Pryor has proposed and to what my friend Jim Cooper and Ron Wyden have proposed.

I have not looked at your point so I don't know, but I have a letter from a physician from Georgia. Following the institution of this program there, he States that he had a patient with a long history of a gastric ulcer that he maintained on zantac successfully. After the program was changed in Georgia, the zantac was reduced. She was not able to get enough prescriptions and she wound up with a massive bleed and she had to have a procedure where she lost her stomach.

I am concerned we not create a system that might adversely affect patients on the Federal level.

Let me ask a question of my good friend, Jim Cooper.

Would your legislation in any way restrict access for patients to much-needed prescription aid?

Mr. Cooper. I thank my friend, Dr. Rowland, for his question.

Our intention is not to interfere in any way with the doctor's prerogative of prescribing whatever drug he or she may choose for a patient. We have a deep respect for the physician's profession and for the great necessity of complete freedom in this area for physicians.

I think that, if anything, our legislation, and it is important to focus on the bill introduced this week, not the earlier Pryor bill which I think the gentleman's constituent is referring to, the legislation introduced this week, I think, would guarantee that freedom for physicians.

Mr. Wyden. Would you yield?

Mr. Rowland. Yes.

Mr. Wyden. I appreciate the gentleman's question. I think the gentleman goes right to the heart of what we want to get out in terms of this new version. I think laymen, not someone like yourself who is a physician, for us these are difficult terms.

There are two policy questions, one is therapeutic substitution and the second is therapeutic equivalents.

What is different, Doctor, from the legislation that we have introduced as opposed to the original Pryor bill is that there is no therapeutic substitution in the new bill that we have introduced.

This means that a physician can direct that a specific drug be prescribed. It is the physician's call.

We also made a change with respect to the issue of therapeutic equivalence. So what this means is now there will not be a committee in effect making decisions about which drugs are preferred.

That was something that I felt very strongly about in terms of the difference between the second version and the earlier version. Unfortunately, some of the drug concerns are still out misrepresenting that the first effort is what is pending but with respect to the new bill that Mr. Cooper and I introduced several days ago, there is no therapeutic substitution, no therapeutic equivalence. Those are the two major differences between the new bill and what was introduced on the Senate side.

Mr. Rowland. Thank you. Would this legislation that you propose in any way establish a national drug formula area where the cheapest drug would be the preferred drug in the Medicaid program regardless of what may be best for the patient?

Mr. Cooper. In answer to the gentleman's second question, I think the reverse is the likely outcome of our legislation. In other words, our legislation would have the effect of opening up existing State formula areas and allowing a wider choice than is currently available to physicians in the States which have closed formula areas.

We put strong incentives in our bill for all the drug companies to participate in the program so that patients can receive the benefits of all drugs.

Mr. WYDEN. Just to amplify, not only would it not create that kind of restrictive national formula, but it would not go to anything like a P&T committee or something like what this legislation has been misrepresented as being.

I think you have hit two of the questions that are essential in terms of describing the mechanics of how this would work.

Mr. ROWLAND. Thank you.

[The prepared statement of Mr. Towns follows:]

PREPARED STATEMENT OF HON. EDOLPHUS TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Thank you Mr. Chairman.

We are considering this round of Medicaid budget initiatives under painfully tight budget constraints on the one hand and under the pressure of greater health care needs and costs on the other.

These circumstances force us to focus more intently on the accountability of any new initiatives we decide to fund. Although we must naturally allow for some trial and error in implementing any new initiative, we can no longer afford that approach in the long term. States must now implement the knowledge gained from demonstration projects in delivering quality, cost-effective services, and the Federal Government has to come up with a means to monitor States' adherence to higher standards over the long run.

On the State level that means maintaining a commitment to effective, quality care. Any new Medicaid spending must also be cost-effective over the long term, which means it must be aimed at preventive measures as well as immediate health care needs.

The sad fact is that we know we must spend more on incarcerating women. In 1990, there are triple the number of women in prison just a decade ago, with 60 percent serving time for drug-related offenses.

We know we must spend more to reduce infant mortality and improve child health. The nation now faces the prospect of caring for hundreds of thousands of drug-exposed infants, with GAO citing an estimated cost of up to $750,000 for the first 18 years of life.

We know that we must spend more on foster care placements for children, which have risen an estimated 30 percent nationally since 1986. The surge in foster care is largely attributed to maternal or family substance abuse, with abused and abandoned children being dubbed "orphans of the living".

We could reduce or prevent all the aforementioned social costs by providing comprehensive health and social services to families affected by substance abuse. Drug Secretary Bennett's white paper on understanding drug treatment names residential treatment as the ideal treatment modality for pregnant addicted women. However, only 11 percent of pregnant women who need substance abuse services are getting it, and almost no programs for substance abuse are willing to treat pregnant women or provide residential treatment where mother and child can live together.

The National Women's Law Center has pointed out that residential treatment programs cost about the same as incarceration, but provide additional health benefits for the mother and child. In two Pennsylvania programs surveyed, one over a decade old, costs ranged from $75 to $90 per day, per family. This translated into a cost of $14,000 per family for the average stay of 6 months.

When we compare these costs with the costs of social services to families who could benefit from treatment in a residential setting, we can see that our current means of dealing with the crises are shortsighted and wasteful. It costs $17,000 per year, on the average, to incarcerate just one of the thousands of women who are imprisoned each year for drug-related offenses. To that, we can add the cost of foster care for the children of many of these women in prison, which can range and cost as much as $5,000 a year for each child. Finally, the cost of providing medical care drug-exposed infants is an estimated four times greater than for infants with no indication of drug exposure.

The Health Care Financing Administration has recently released a statement outlining existing Medicaid-reimbursable substance abuse treatment services.

Among the recommended services for the substance abuse treatment are impatient hospital detoxification, treatment for adolescents and the elderly at psychiatric hospitals, and the use of facilities not subject to the IMD exclusion, namely facilities with less than 17 beds.

Unfortunately, these categories of services have two crucial drawbacks. First, they number among the most expensive of all treatment settings. Inpatient hospital care could cost hundreds of dollars each day and require a significant (and therefore prohibitively expensive) period of confinement.

In addition to the incredible expense of Medicaid-covered inpatient substance abuse treatment and the limited capacity of outpatient treatment, these treatment options represent only a part of a patchwork of services vital to the pregnant substance abusers.

The Health Care Financing Administration recommendations, even if implemented to maximum effect, would still fail to provide the kind of comprehensive services which the experts and the general accounting office recommend as the most effective treatment modality for pregnant substance abusers.

I have introduced a bill, the Medicaid Family Care Act (H.R. 5536), which would provide comprehensive substance abuse treatment services to pregnant women in a residential setting. This legislation would ensure minimum standards of care through a system of comprehensive services required in each State's plan for compliance with the act. New York and Illinois have taken substantial steps to make such services a reality, but most States are not dealing with the problem of the pregnant substance abuser in an effective manner.

The Medicaid Family Care Act would allow States to provide the most cost-effective means known for meeting the broad demand for health care and social services associated with substance abuse among pregnant women.

The Medicaid Family Care Act would help States attack the cycle of addiction where it often begins, that is, in the family. And because services are aimed at helping the entire family, by directing comprehensive care toward pregnant addicts and their children, this proposal could save us more social service outlays over the long term than the patchwork of maternal, child and family services now in place.

Pennsylvania and Illinois, two States which have already funded substance abuse treatment for pregnant women and women with children, have praised this legislation, with two chief reservations. Medicaid and substance abuse agencies in both States have questioned the harshness of the bill's maintenance of effort provision, which would require States to spend at no less than current funding levels for existing treatment programs, and without a Federal match for any funding below current levels of spending. The provision as it appears in H.R. 5536 would therefore penalize those States which have made the greatest strides towards implementing comprehensive substance abuse treatment services, Illinois and Pennsylvania among them.

I am prepared to substitute a more generous maintenance of effort provision for the one currently in the Medicaid Family Care Act, to ensure the participation of those States who have made significant investment in comprehensive and residential substance abuse treatment.

I urge my colleagues to cosponsor H.R. 5536, and to actively support long-term solutions to the problem of substance abuse among pregnant women.

Mr. Waxman. Our next panel will address three different issues.

Dr. Sidney Wolfe for almost 20 years has been the advocate of consumers on these issues. He is also the winner of McArthur Fellowship for Promising Individuals. McArthur individuals are not only given a substantial income for 5 years, but also comprehensive health insurance.

Susan Galbraith, Coalition on Alcohol and Drug Dependent Women and Their Children. Ms. Galbraith will testify on the Medicaid Family Care Act, H.R. 5566, sponsored by Representative Towns, which would give States the option of giving control substitute treatment services for pregnant women.

Mayor Dinkins testified Monday for this bill.

Marie Ansak is executive director of On Lok, Inc. that takes responsibility for the care of frail elderly eligible for Medicare and Medicaid. For her work in developing this project, Ms. Ansak received the $25,000 Gustave O'Linhart award given by the Institute of Medicine of the National Academy of Sciences.

She will testify on the efforts to bring the On Lok services to communities other than San Francisco.

We welcome you. Your written statement will be included in the record. We would ask each of you to limit your oral presentation to no more than 5 minutes.

Dr. Wolfe, since you have to leave immediately after your presentation, we would like to start with you.

STATEMENTS OF SIDNEY M. WOLFE, DIRECTOR, PUBLIC CITIZEN HEALTH RESEARCH GROUP; SUSAN GALBRAITH, DIRECTOR, COALITION ON ALCOHOL AND DRUG DEPENDENT WOMEN AND THEIR CHILDREN; AND MARIE-LOUISE ANSAK, EXECUTIVE DIRECTOR, ON LOK

Mr. **Wolfe**. Thank you for inviting me to testify before this hearing.

Multiple prescriptions are possibly the best idea, based on their record of success, that I have ever seen affecting the price of medicine in the United States. I must strongly commend the 21-month-old effort in New York State, which has extended not only to the narcotics, amphetamines and barbiturates eight other States have under this program, but they have added benzodiazepines like xanax.

In nine States—New York, California, Texas, Indiana, Hawaii, Michigan, Illinois, Rhode Island and Idaho—laws or regulations are in effect which require multiple—usually triplicate—prescription forms to be filled out by doctors who are writing prescriptions in their offices for any schedule II controlled substance—drugs such as morphine, codeine, barbiturates, amphetamines and other prescription drugs which are usually addictive, otherwise dangerous and are subject to abuse. By pressing a little harder, the doctor makes two extra copies of the prescription so that not only the pharmacist, but the State government and the physician will also have a copy.

According to officials from the Drug Enforcement Agency, after these laws have been in effect for several years, there has been an approximately 50 percent decrease in the number of prescriptions written for the controlled drugs.

I am now going to focus on tranquilizers and sleeping pills. What is the impact of overprescribing of these drugs?

Ten thousand hip fractures due to falls caused by these drugs;

Seventy-five thousand older adults with drug-induced or drug-worsened mental deterioration—dementia caused by these drugs;

According to a study by the Drug Enforcement Agency, there were 60,148 occasions in American hospital emergency rooms in which these drugs were listed in association with drug overdose problems;

A variety of other kinds of serious impairment including: addiction, daytime sedation, confusion, increased risk of an auto accident, slurred speech and, especially in combination with alcohol, death.

A large proportion of these serious injuries and deaths could be prevented if the prescribing of these drugs was done more carefully than is now the case which would also mean, as strikingly seen in New York, a significant decrease in prescribing.

I would like to comment about the New York program. Has it worked? The series of charts at the end of the testimony, I think, speak to this issue. The first chart looks at the total number of prescriptions written in the whole United States for this class of drugs, sleeping pills and tranquilizers.

In 1988, it was 82 million. It went down to 74 million in 1989. In New York State with this program having gone into effect January 1, the beginning of 1989, by the end of 1 year, one of the groups of people who get prescription drugs, the State employees, the Empire Plan, there was a 37 percent decrease in these prescriptions in 1 year.

Medicaid, again a State-Federal program, there was a 59 percent decrease in 1 year, contrasted to the national average going down just about a sixth as much for these prescriptions.

One of the objections raised is it is going to keep doctors from prescribing drugs that patients need. In fact, quite the opposite is true. One of these drugs is not a sleeping pill or tranquilizer, but is used for treating epilepsy.

This drug actually went up in prescriptions during that year. It has become more popular, and no one could argue there is any impairment.

In the United States, in 1988 and 1989 alike, there were about 60,000 mentions of people in emergency rooms using these drugs. It didn't change at all.

In New York State though, just in the Buffalo and metropolitan New York areas, in 1 year after the program went into effect, there was a decrease of 1,000 fewer emergency room instances where these drugs were involved just in those two cities. Statewide, the number is much larger.

And, finally, the last chart showing that just in Medicaid alone, over $11 million alone were saved on benzodiazepines. A small amount went into increases in other less dangerous categories of drugs.

We would estimate if you add in not only the cost for drugs for Medicare and State employees, but the cost of drugs for older people, which are subsidized in New York, we would save about $100 million a year, just in New York State.

In summary, I would just like to say that we strongly support passage of Federal legislation that would protect people in every State in the country as New York and to a lesser extent these other eight States, have done for people in their State.

This is a simple, inexpensive piece of legislation. New York spent for this piece of legislation $1.6 million in a year, of which a certain amount came back because the doctors pay 25 cents a piece for the prescriptions. It is very cost-effective and it will save an enormous amount of money.

I have never seen anything as effective as this, and I strongly hope your committee and comparable committees in the Senate will quickly pass legislation which will do for the whole country what has already happened in a few States.

[Testimony resumes on p. 285.]

[The prepared statement of Mr. Wolfe follows:]

TESTIMONY OF SIDNEY M. WOLFE, M.D.
DIRECTOR, PUBLIC CITIZEN HEALTH RESEARCH GROUP
WASHINGTON, D.C.
ON PROPOSED LEGISLATION TO REQUIRE TRIPLICATE PRESCRIPTIONS
FOR ALL CONTROLLED SUBSTANCE PRESCRIPTION DRUGS
BEFORE HOUSE HEALTH SUBCOMMITTEE
SEPTEMBER 14, 1990

Chairman Waxman and members of the Subcommittee, thank you for the invitation to present testimony on this important public health protection and cost-saving legislation which is under consideration by your Subcommittee.

At the outset, I must strongly commend the now 21-month-old effort in New York State for benzodiazepines, along with older systems in the 8 other states who, with New York, have previously implemented multiple prescription programs. These programs are the most important improvements I have ever seen in the out-of-hospital practice of medicine, the quality of prescribing by doctors and, as seen clearly in this testimony, in saving hundreds of millions of dollars of dangerously wasted money.

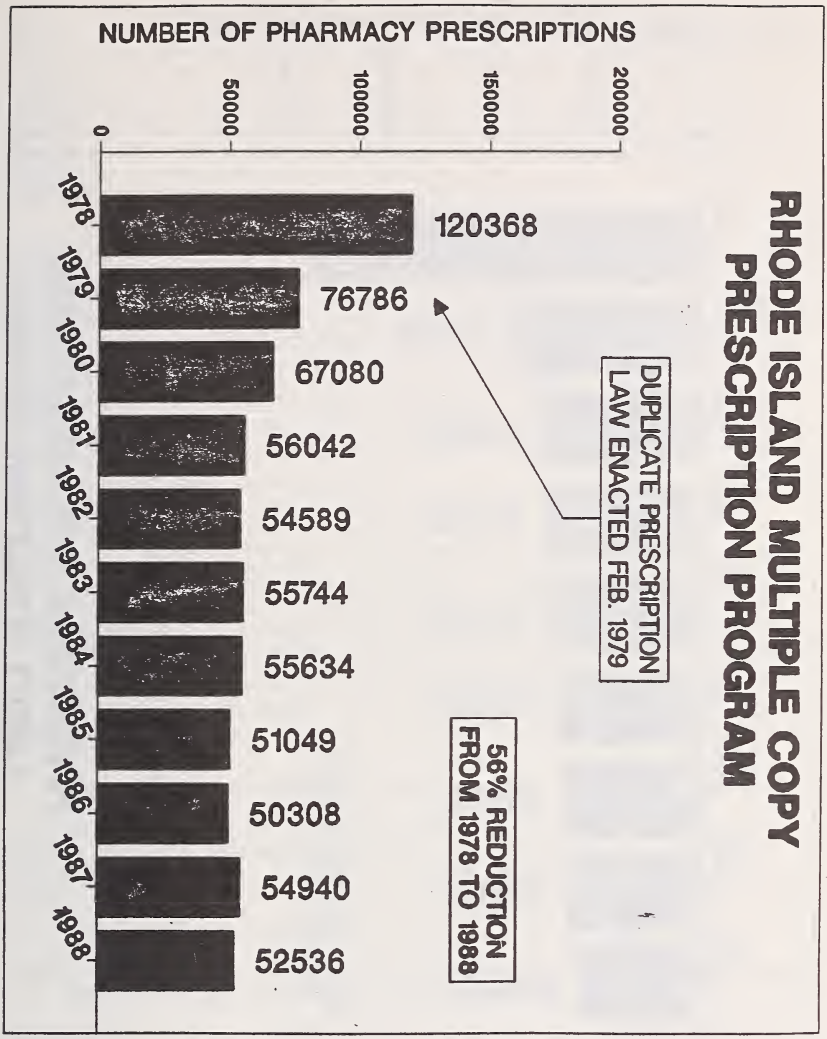
Given that the number one drug abuse problem in this country --in terms of the number of people affected and the severity of the effects---involves legal prescription drugs, the triplicate prescription programs are the most successful effort yet in our war on drugs.

In nine states, New York, California, Texas, Indiana, Hawaii, Michigan, Illinois, Rhode Island and Idaho, laws or regulations are in effect which require multiple (usually triplicate) prescription forms to be filled out by doctors who are writing prescriptions in their offices for any Schedule II controlled substance--drugs such as morphine, codeine, barbiturates, amphetamines and other prescription drugs which are usually addicting, otherwise dangerous and are subject to abuse. By pressing a little harder, the doctor makes two extra copies of the prescription so that not only the pharmacist, but the state government and the physician will also have a copy.

According to officials from the Drug Enforcement Agency (DEA), after these laws have been in effect for several years, there has been an approximately 50% decrease in the number of prescriptions written for the controlled drugs.

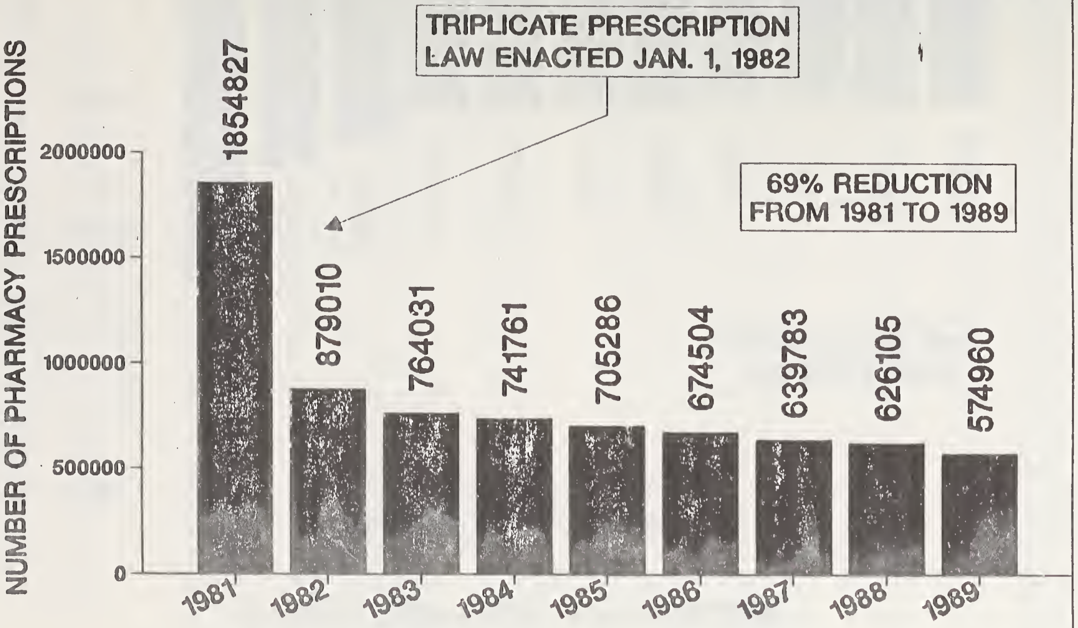
On the next two pages are examples of this for the Schedule II drugs in two states, Rhode Island and Texas.

In four of these states--New York, California, Illinois and Indiana, the state also has the authority to apply the triplicate prescription regulation to drugs in Controlled Substance Act


RHODE ISLAND MULTIPLE COPY
PRESCRIPTION PROGRAM
NUMBER OF PHARMACY PRESCRIPTIONS
0
50000
100000
150000
200000
1978
120368
1979
76786
1980
67080
1981
56042
1982
54589
1983
55744
1984
55634
1985
51049
1986
50308
1987
54940
1988
52536
DUPLICATE PRESCRIPTION
LAW ENACTED FEB. 1979
56% REDUCTION
FROM 1978 TO 1988

2

TEXAS MULTIPLE COPY PRESCRIPTION PROGRAM



TRIPLICATE PRESCRIPTION LAW ENACTED JAN. 1, 1982

69% REDUCTION FROM 1981 TO 1989

Schedules III or IV as well. Thus far, only New York State has gone outside of the Schedule II drugs mentioned above to include all of the benzodiazepines: drugs such as the tranquilizers Valium, Librium, Xanax, Ativan, and Tranxene and sleeping pills such as Dalmane, Halcion and Restoril. But New York had to successfully weather legal challenges from major drug companies producing these drugs (Roche, Abbott, Wyeth and Upjohn) and from the New York State Medical Society before the requirement for triplicate prescriptions for benzodiazepines went into effect on January 1, 1989.

Although most of the remaining remarks will apply to benzodiazepines, the principles are relevant to legal or illegal misuse or misprescribing of any of the drugs covered by triplicate prescription laws or regulations. As mentioned above, there is much more experience in more states with the application of triplicate prescriptions to Schedule II drugs and the record is clear that the programs are quite successful in reducing the illegal uses and misprescribing of these drugs without any credible evidence that either patients or physicians have been prevented from the use of those controlled prescription drugs which are properly prescribed for appropriate periods of time.

It has never been the position of the Public Citizen Health Research Group that the 11 benzodiazepine sleeping pill and tranquilizer drugs should be banned, rather that they are prescribed more often than is necessary considering the limited duration of time for which they have been shown to be effective and the serious risks which they pose. Whereas these risks may be outweighed by their benefits when they are properly prescribed, for the large number of people who get them through their diversion from originally legitimate or illegal channels or the probably even larger number of people for whom they are prescribed inappropriately, the risks outweigh the benefits. It is to protect these people, for whom benzodiazepines are not properly prescribed, that the triplicate prescription regulation is intended.

WHAT IS THE IMPACT OF OVERPRESCRIBING OF THESE DRUGS?

Based on data from published studies done in the United States, we have estimated the following toll, just in older adults, from the use of benzodiazepine tranquilizers and sleeping pills:

* 10,000 hip fractures due to falls caused by these drugs;

* 75,000 older adults with drug-induced or drug worsened mental deterioration (dementia) caused by these drugs;

* As shown below, in 1989 alone, according to a study by the Drug Enforcement Agency, there were 60,148 occasions in

American hospital emergency rooms in which these drugs were listed in association with drug overdose problems.

* A variety of other kinds of serious impairment including: addiction, daytime sedation, confusion, increased risk of an auto accident, slurred speech and, especially in combination with alcohol, death.

A large proportion of these serious injuries and deaths could be prevented if the prescribing of these drugs was done more carefully than is now the case which would also mean, as strikingly seen in New York, a significant decrease in prescribing.

HAS THE NEW YORK TRIPLICATE PRESCRIPTION REGULATION FOR BENZODIAZEPINES WORKED?

The following data were obtained from the New York State Health Department, the National Prescription Audit (IMS, Inc, Ambler,Pa.) and the Drug Enforcement Agency in the U.S. Department of Justice and summarize the data presented in the charts attached to the back of the testimony in charts C1 through C9:

PRESCRIPTIONS FOR BENZODIAZEPINES: U.S. vs New York

From 1988 to 1989, nationwide, there was a slight (9.8%) decrease in the total number of benzodiazepine prescriptions filled in American retail drug stores from 82 to 74 million (C1) **but for the New York State employees, family and retiree plan called Empire, there was a 37% decrease from 1988 to 1989 (C2), a decrease almost five times greater than seen nationally. For New York Medicaid, there was a 59.3% decrease from 1.56 million prescriptions in 1988 to 630,000 in 1989 (C3), more than six times larger than the national decrease that year. This** 930,000 prescription decrease was only slightly offset by increases in prescriptions of non-benzodiazepine tranquilizers and sleeping pills of 189,000 from 1988 to 1989.

By the end of the first year after the regulation went into effect, **there was a 40% decrease in the percentage of people in New York's state-subsidized elderly drug reimbursement plan, EPIC, who got prescriptions for benzodiazepines.** The % of plan members who got a benzodiazepine prescription went from 20.9% of all members during the last 3 quarters of 1988 to 12.6% by the last quarter of 1989 and was still decreasing at that time.

Of great interest to those who, without evidence, complain that this kind of program might curtail necessary prescribing of these drugs is the case of clonazepam, the only drug in the benzodiazepine family which is not a tranquilizer or sleeping pill but is used to treat seizure disorders in people with epilepsy. Unlike the sharp decreases in these latter kinds of drugs shown above, the prescriptions for clonazepam, the benzodiazepine used to treat epilepsy, actually rose from 1988 to 1989 in the New York State Medicaid program (C4) and in the state employees program.

EMERGENCY ROOM DATA FOR BENZODIAZEPINES: U.S. vs New York

As can be seen in chart C5, for the entire country, there was no decrease, in fact a slight increase from 1988 to 1989 in emergency room mentions through the DAWN (drug abuse warning network) system for benzodiazepines. These data are based on surveys of what drugs were being used by people who wind up with drug abuse problems in emergency rooms. For 1989, nationwide, there were 60,048 mentions for benzodiazepines and the number had risen slightly to 60,148 by 1989.

In New York, at least the part of the state represented by the metropolitan Buffalo and New York City areas, there was a 39% decrease in benzodiazepine emergency room mentions as seen in chart C6. From a level of 2611 mentions in 1988, with the start of the triplicate prescription program on January 1, 1989, the number decreased to 1590 for that year.

Although there was a slight increase during 1989 in prescriptions for non-benzodiazepine tranquilizers and sleeping pills in New York accompanying the much larger decrease in benzodiazepines, there was actually a decrease in emergency room mentions for these drugs in New York State, going from 506 in 1988 to 457 in 1989 even though nationally the number increased from 12,530 to 13,595. These changes can be seen in charts C7 and C8.

Other gains cited by the New York State Health Department include:

* 95% reduction in benzodiazepine use by one group of about 3400 patients suspected of diverting almost 250,000 prescriptions annually into illicit use.

* 76% reduction in prescriptions dispensed by pharmacies suspected of being "pill mills."

* Increase in "street" prices of 2 to 5 times for benzodiazepines, indicating a "drying up" of supplies on the street.

COST SAVINGS: New York State

There are many parts of the answer to the question of cost savings for implementing such a program but the ones which can be measured thus far are very telling. As seen in chart C9, there was a saving of 11.2 million dollars in the Medicaid program alone in terms of less state purchases for benzodiazepines. Although about 1/3 of this dollar amount was offset by increases in other non-benzodiazepine tranquilizers and sleeping pills, there was still a net saving to New York Medicaid of 7.4 million dollars in one year.

This does not include additional savings from the state employees and older citizen plans nor from the thousands of fewer emergency room visits, decreased hip fractures, loss of memory and other serious adverse effects prevented by the initiation of this revolutionary program. If one includes all citizens of New York State, not those in state-funded programs, I would estimate that the savings in reduced purchases of drugs and decreased drug-induced diseases and injuries could well approach 100 million dollars.

These enormous decreases in the prescribing of benzodiazepines, which can not solely be accounted for by a reduction in illegal prescribing, is consistent with a decrease in the amount of overly-lengthy prescriptions and/or a decrease in the third category of misprescribing, namely treating the normal stress of daily living with benzodiazepines.

It is clear that causing doctors to pause, momentarily, as they write the triplicate prescription for any of these drugs, will add to their realization that these are medications with significant risks as well as benefits. To the credit of doctors in New York State, the first six months of the regulation being in effect have already seen a significant statewide decrease in prescribing.

THREE KINDS OF MISPRESCRIBING OF TRANQUILIZERS AND SLEEPING PILLS

There are three categories of benzodiazepine misprescribing which the New York regulation has attempted to cure:

First, the diversion onto the so-called street(s) of drugs originally prescribed by a physician who knows or should usually know that these are going to be diverted and resold on the street, often for large sums of money. This is often referred to as illicit use although the initiator of this is a licensed physician engaging in unethical if not illegal, activity. It must be noted that in New York State, as well as in the few other states which are seriously engaged in efforts to discipline doctors whose practices of medicine may be endangering their patients, a common reason for license revocation or suspension is the gross over-prescribing of drugs such as benzodiazepines or narcotics. The prescribing practices of these doctors, combined with the willing filling of these prescriptions by friendly pharmacists, are sometimes referred to as "Pill mills."

Unfortunately, especially with drugs such as benzodiazepines which are not as rigorously controlled by the federal Controlled Substances Act as narcotics, these doctors or pharmacists are often not caught until they have prescribed or dispensed enormous quantities of drugs which wind up on the street or in circles of benzodiazepine-addicted people. An additional type of illegal activity which "diverts" benzodiazepines is the forging of prescriptions.

The logical deterrent effect of a triplicate prescription requirement, as demonstrated with the previous use of such forms for drugs such as amphetamines, on those doctors and pharmacists who are much more likely to get caught with such a requirement, has already been seen in New York State in the brief time since the regulation went into effect. A memo from John Eadie, Director of the Division of Public Health Protection to Health Commissioner Dr. David Axelrod, dated March 1, 1989 documents this. In 21 pharmacies in the Bronx and Manhattan suspected of being part of "Pill Mills" involved in the diversion of benzodiazepines, there was a marked decrease in the number of benzodiazepine prescriptions filled in one week less than a month after the regulation was finally allowed to go into effect (in comparison with the number of prescriptions filled in a week shortly before the regulation went into effect). To quote from the memo, "In the center of the "Pill Mills," Manhattan and the Bronx, the decrease was 79%, in Queens and Brooklyn, 67% and upstate, where less diversion had been suspected, 39%."

Although there has been a dramatic decrease in the prescriptions for benzodiazepines, correlated closely with the extent to which certain geographic areas are known to be populated with "Pill Mills," there is no evidence that the legitimate prescribing of these drugs has been adversely affected by the regulation.

A second category of inappropriate prescribing involves prescriptions written without any intention or much possibility of diversion. These prescriptions are written for legitimate indications such as treating severe anxiety or sleeping disorders but, due to carelessness on the part of the doctor and unawareness or unwillingness to adhere to the approved labelling on the drugs, the prescriptions are continued for periods of time far in excess of those for which there is evidence that the drugs are effective.

Using data from national surveys of the use of these drugs, we estimate that over 3.0 million adults aged 18 to 79 are being given one or more of these drugs daily for one year or longer. This pattern of prescribing has occurred despite the fact that the Food and Drug Administration-approved labelling for these drugs says that there is no evidence that any of the tranquilizers work for more than 4 months nor that the sleeping pills work for more than 4 weeks.

The third category of misprescribing involves doctors giving patients benzodiazepines for the normal and understandable stress of daily living, situations which merit attention by doctors, family, friends, clergy and others but which should not be "treated" with these drugs. For the past few years, the labelling for these drugs has stated that "Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic" (1989 Physicians' Desk Reference). There is no evidence that the large amount of prescribing of benzodiazepines for these purposes has decreased as much as it should since the time this label change was implemented.

HOW CAN THERE BE ANY RATIONAL REASON FOR OPPOSING SUCH A PROGRAM?

Even the American Medical Association, which strongly opposes laws which require triplicate prescriptions, admits that "Diversion of prescription drugs for purposes of abuse is a significant contributor to this nation's drug abuse problem and its attendant morbidity and mortality. ("Report of AMA Board of Trustees, 1989, on Curtailing Prescription Drug Abuse While Preserving Therapeutic Use")

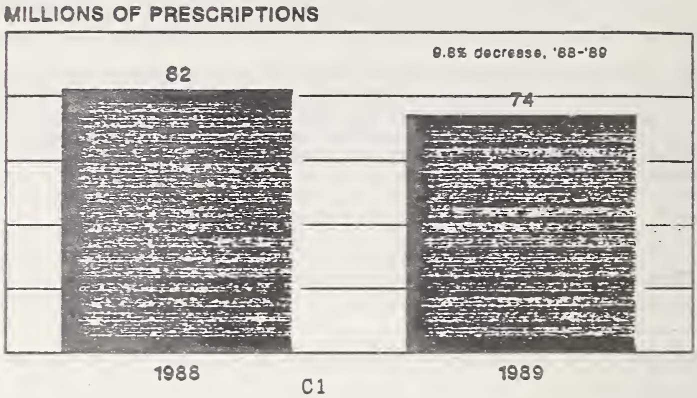
Despite their admission of this serious problem, in December 1989, the AMA Board of Trustees adopted the above report and its recommendations that the AMA:

> "Oppose expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug abuse and their adverse effect on the availability of prescription medications for therapeutic uses."

The above AMA statement opposing multiple prescription programs is filled with false and misleading information. Its pitch and degree of misinformation is similar to that in the ultimately failed legal effort by the New York Medical Society and its partners in the prescription drug industry (Roche, Upjohn, Wyeth and Abbott) to stop the New York State Health Department from implementing its program to require triplicate prescriptions for benzodiazepines. (A New York Court ordered that the program could begin in January 1989.)

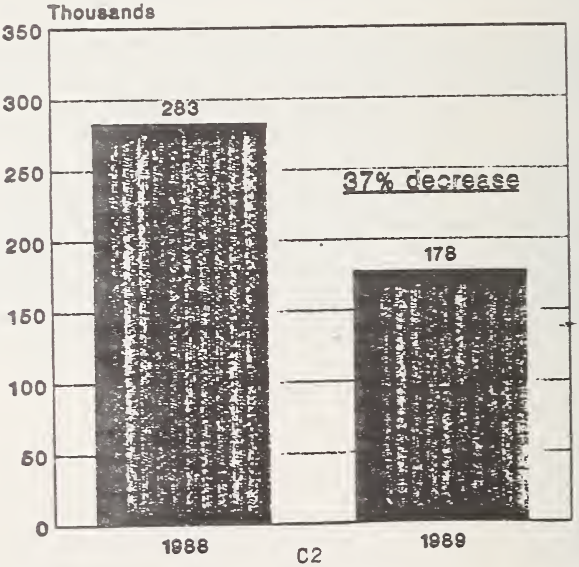
In summary, the important New York regulation requiring triplicate prescriptions for benzodiazepines has already had an important impact in the year since it went into effect. In direct proportion to the decreased use of these drugs, will be a decrease in the preventable adverse effects such as memory loss, falls and hip fractures, addiction, bizarre behavioral problems such as aggression and other serious problems.

We strongly urge passage of federal legislation to allow the entire country to have the benefits that New York and, to a lesser extent, the other multiple prescription states now have. This will not only save an enormous amount of money but, most importantly will bring an increased measure of health protection to the citizens of this country.



Prescriptions for Benzodiazepine
United States: Retail Pharmacies

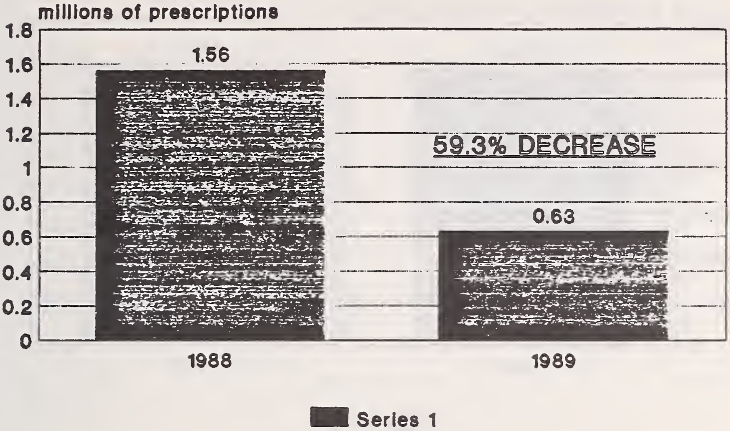
C1



Prescriptions for Benzodiazepine
New York State Employees (Empire)

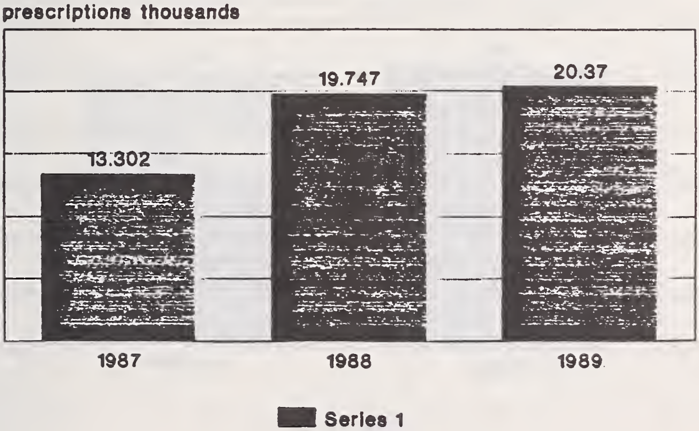
C2

Prescriptions for Benzodiazepines
New York State Medicaid



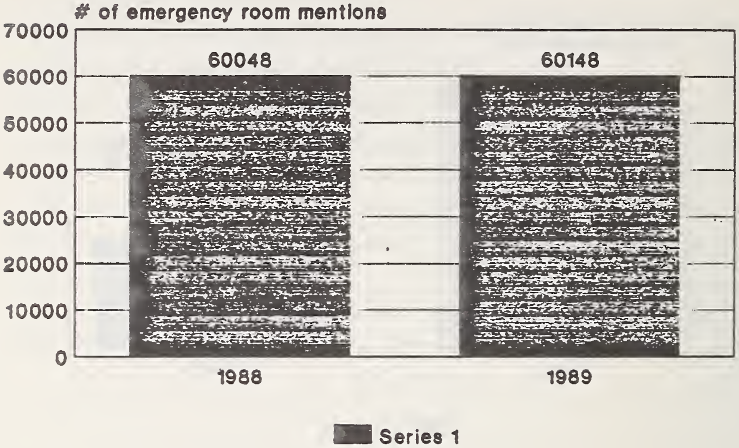
C3

Prescriptions for Clonazepam
epilepsy benzodiazepine: N.Y. Medicaid



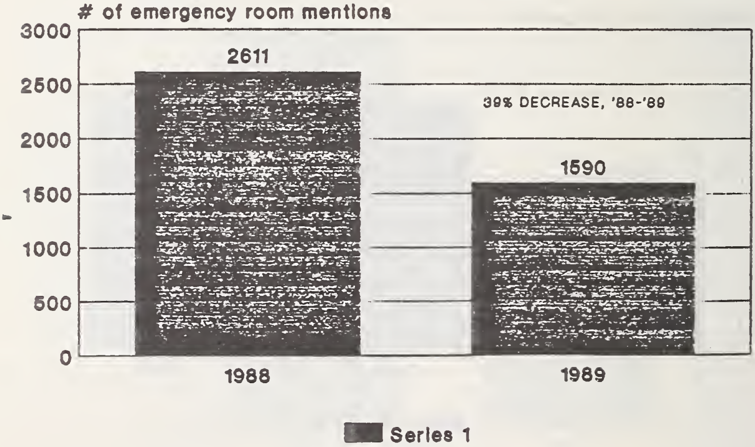
C4

Emergency room data for benzodiazepine tranquilizers and sleeping pills: U.S.



C5

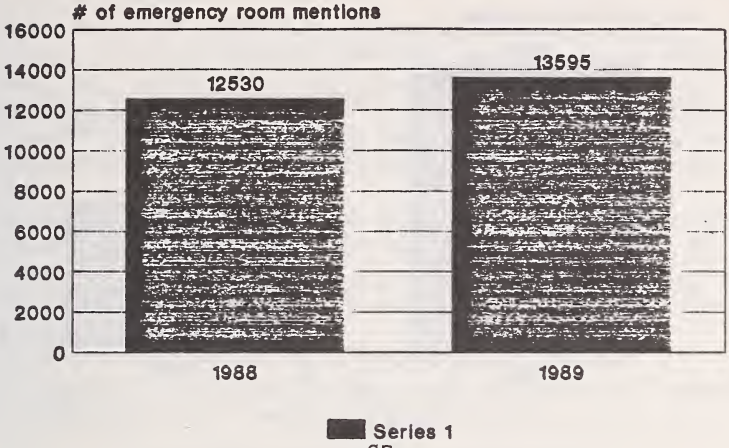
Emergency room data for benzodiazepine tranquilizers and sleeping pills: N.Y.*



C6

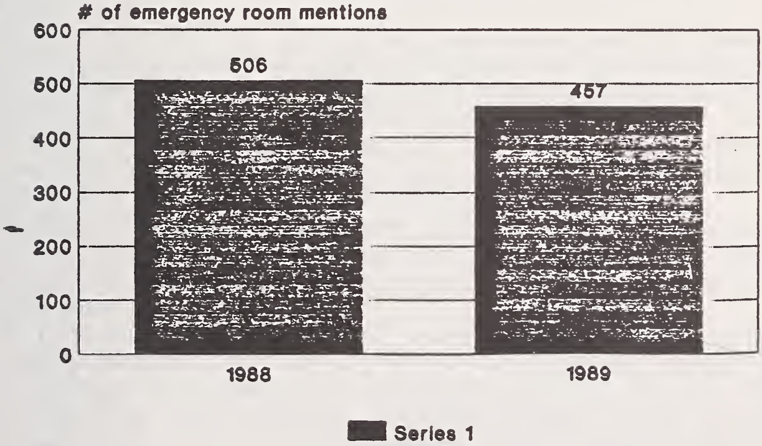
Data for Buffalo and metro N.Y.

Emergency room data for non-benzo tranquilizers and sleeping pills: U.S.



C7

Emergency room data for non-benzo tranquilizers and sleeping pills: N.Y.*

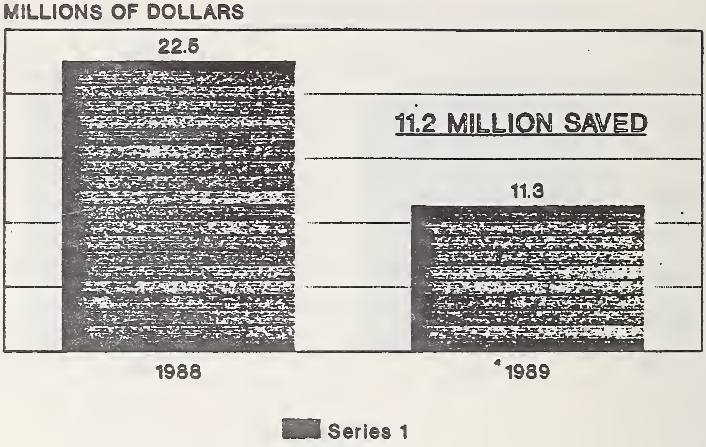


C8

Data for Buffalo and metro N.Y.

Payments for Benzodiazepines

New York State Medicaid



C9

Mr. **Waxman**. Dr. Wolfe, I thank you for your testimony. I know you have to leave. Members of the subcommittee have questions to ask of you. Without objection of the members, I would like to ask that the questions and your responses be in writing for the record, if you would permit.

Thank you, and we appreciate you being with us.

Mr. **Wolfe**. Just one further comment, which is one of the issues that has been raised with some concern, but I think the record really rebuts it, is that people, for example, who need drugs for pain, cancer patients need drugs for pain, will somehow be deprived of getting these drugs if multiple prescription programs are in place.

If anything, there is really no evidence of that. In the States where there are triple prescription programs, if anything, for the drugs that are focused on cancer pain patients, Dilaudid, for example, patients are getting as much or more of these drugs than in States such as Wisconsin.

There is an underprescribing of pain drugs for cancer.

Mr. **Waxman**. Thank you, Doctor, for those additional comments.

We would like to now hear from Ms. Galbraith.

STATEMENT OF SUSAN GALBRAITH

Ms. **Galbraith**. Mr. Chairman and members of the subcommittee, thank you for the opportunity to be here today.

I think that there is little doubt that we are desperately in need of a basic system of care for pregnant addicted women and their children. Yesterday, I met with a primary caregiver from the State of Florida, from Miami, and currently there are over 250 pregnant women who are motivated and ready to seek treatment who have nowhere to go.

There is no question that we are in a real state of affairs in terms of getting pregnant addicted women the kind of treatment that they need and deserve. Alcoholism and drug dependency treatment is one of the most important prescription strategies we can implement in this country to prevent low birth weight, transmission of AIDS and the chronic physical and emotional disabilities associated with prenatal exposure to alcohol and other drugs.

Traditional funding mechanisms such as the 1980 M.S. block grant and M.C.H. block grant, have not been adequate to meet the needs of this population. That is even given your leadership on an annual basis.

We have studied reimbursement policy for alcohol and drug services under Medicaid, and one of the profound gaps in funding is for the financing of comprehensive residential services. The main barrier preventing that funding is the IMD exclusion, which prevents Medicaid from funding institutions for mental diseases that have anything less than 16 beds. And both alcoholism and drug addictions are defined as mental diseases by HCFA.

Programs suitable for women and their children are on average between 30 and 34 beds if we are going to serve women and their kids under the same roof. Comprehensive residential services are critical for this population.

To begin with, most pregnant addicted women need a range of services, including prenatal care, addictions treatment, housing and employment assistance, and child care. Services in this country are fragmented and it is difficult for women who are impoverished to travel all over their town on public transportation with their children to try to put together a decent set of services.

Many pregnant women are addicted to more than one drug, have been addicted for a long period of time, and are going to need long-term habilitation before treatment is going to be successful. This is not going to happen in out outpatient basis and it is unlikely to happen on a limited 21- to 28-day residential stay.

Finally, most women who would be touched by this proposal are living in drug-infested communities. Their homes and communities are not safe, and they need a drug-free environment and the support of other women in recovery to stay drug free and build their lives.

Our proposal would simply expand Medicaid to provide comprehensive residential treatment for addicted women and their kids. Most of this proposal is embodied in Representative Towns' bill, the Medicare Family Care Act, H.R. 5536, and its companion bill on the Senate side, S. 3002.

These proposals would allow, at a State's option, Medicaid to cover comprehensive services for pregnant women and their children, and caretaker parents of those children.

Under a State-approved plan, providers would be required to provide comprehensive services to pregnant women and their children. CBO estimated the first cost would be $17 million, and the 5-year cost would be $542 million. We have concerns about some of the CBO assumptions, and would like to let committee members know our sense of what it costs to provide these services today ranges from $75 to $90 per family per day.

We all heard Dr. Wolinsky testify on Monday about HCFA's plans to establish a small demonstration project. While we applaud HCFA's concerns, we have serious reservations about a demonstration. We have a crisis in maternal and child care related to drug addiction.

States are currently enacting legislation to amend child abuse statutes to define drug use during pregnancy as child abuse. Women are being treated as criminals in some States because they are addicted to drugs while pregnant and have no access to care.

We can hardly afford to respond to this gross discrimination in health care and this crisis through a modest demonstration project.

Mr. Chairman, I want to thank you for this opportunity to testify today, and I just want to point out that we have been engaged in a war on drugs in this country for quite a few years, and we have failed dismally in those efforts.

We have yet to establish the basic system of care that would allow alcoholics and drug addicts to come into treatment and begin to do something to turn their lives around.

Thank you very much.

[Testimony resumes on p. 309.]

[The prepared statement and attachments of Ms. Galbraith follow:]

Susan Galbraith
Director
Coalition on Alcohol and Drug Dependent Women and Their Children

Mr. Chairman and members of the Subcommittee, it is an honor to be here to testify before you on the need to expand Medicaid to support comprehensive residential treatment programs for pregnant alcoholic and drug dependent women and their children. My name is Susan Galbraith. I am the Director of the Coalition on Alcohol and Drug Dependent Women and Their Children. I have worked as an advocate for alcoholic and drug dependent individuals and their families as the Associate Director of Public Policy for the National Council on Alcoholism and Drug Dependence. I have worked as a program director and as a counselor in both residential and outpatient programs serving alcoholic and drug dependent women and their children.

The Coalition on Alcohol and Drug Dependent Women and Their Children was organized by the National Council on Alcoholism and Drug Dependence (NCADD) in May 1989 in response to the trend spreading across the nation to punish women who are alcoholic and drug dependent and pregnant rather than intervene and provide treatment. We found this trend particularly alarming since very few states in the nation have programs which treat pregnant alcoholic and drug dependent women and their children.

The Coalition is committed to enhancing prevention and treatment services for women and children. There are currently 37 organizational members and an additional 30 groups who participate in the Coalition. Concerned citizens and state based groups are also members. The range of groups includes many of the major national organizations concerned with the health and well-being of women and their children (a full list of Coalition members and a Statement of Purpose is attached).

There is a crisis of maternal drug addiction in America today. In recent months the news media has been filled with articles reporting this sad and tragic story. The facts are alarming. Estimates indicate that anywhere between 100,000 and 375,000 infants are exposed to drugs prenatally each year. In addition to the infants who are exposed to illegal drugs, at least 5,000 infants are born each year with full blown Fetal Alcohol Syndrome (FAS) and another 35,000 with alcohol related birth defects. In 1988, an estimated 5 million women of childbearing age used illicit drugs. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) estimates that 1 out of 6 women of childbearing age may drink enough to threaten a healthy pregnancy. The National

Association of State Alcohol and Drug Abuse Directors (NASADAD) reports that the publicly funded treatment system in this nation is only able to serve about 11 percent of the 280,000 pregnant alcoholic and drug dependent women in need of treatment.

Even when addicted women seek treatment, they are especially discriminated against if they are poor and pregnant. A 1989 study by Wendy Chavkin, M.D. of 78 New York city drug treatment programs found that women claiming to be pregnant and addicted were refused service by 54 percent of programs, 67 percent denied treatment to pregnant addicts on Medicaid and 87 percent denied treatment to pregnant women on Medicaid addicted to crack.

We know that the treatment, health care, child welfare and foster care systems are all beseiged with families in need of comprehensive services and that they have no place to turn. And we know that by not treating these problems we are only creating even greater economic and social problems in the future. A 1990 GAO study of 10 hospitals highlights the tremendous costs of caring for infants who are exposed to drugs prenatally.

o Hospital costs were four times greater for infants who were exposed to drugs than those for infants with no indication of drug exposure.

o About 1,200 of the 4,000 infants born exposed to drugs were placed in foster care. The cost of 1 year of foster care for these 1,200 infants is about $7.2 million.

o The Florida Department of Health and Rehabilitative Services estimates that for those drug exposed children who show significant physiologic and neurologic impairment total service costs to age 18 could be as high as $750,000.

Throughout this hearing, we have heard about the close association between low-birth weight and infant mortality. Low-birthweight is one of the most significant outcomes of drug use during pregnancy. In the 1990 GAO study, the rate of low birth weight among infants exposed to drugs prenatally was at least twice as great as infants not identified as drug exposed. The rate of low birthweight infants ranged from 25 to 31 percent among drug-using women and 4 to 11 percent for women not identified as using drugs. We have found that low birth weight and prematurity, which often require expensive neonatal intensive care, are minimized by drug treatment for pregnant women before the third trimester.

We have also heard about the increasing numbers of women and infants who are testing positive for HIV. These are primarily African American and Hispanic women and their children who are either iv drug users or partners of iv drug users. Drug treatment is one of the most important interventions for preventing the transmission of AIDS. It can also help to prevent the prenatal transmission of the virus. Unfortunately, comprehensive drug treatment for pregnant women is virtually non-existent in communities where the rates of HIV infection are highest.

The Subcommittee is well aware of the scope of the problem of alcoholism and drug addictions among women and more specifically, pregnant women. Mr. Chairman, you have been a leader in pointing out the absence of treatment interventions for this population. You have worked diligently for years to pressure states to be more responsive to the needs of women. The women's set-aside of the ADMS block grant which was enacted in 1984 under your leadership has represented a commitment on the part of Congress to rectify the serious disrimination women face when they seek treatment. Unfortunately, the block grant and the set-aside do not provide a source of stable and ongoing funding for services for poor addicted women and their children. In fact, we know that many states have been recalcitrant in their duty to implement the set-aside. And even if the set-aside were uniformly implemented, it would not provide the stable funding base needed to establish a system of care for women and their children.

We desperately need to develop a basic system of care for pregnant alcoholic and drug dependent women in order to successfully intervene and prevent the long term and devasting impact of alcohol and drugs on women, their children and families. Alcoholism and drug dependency treatment is the most important prevention strategy which we can implement to prevent low birthweight, transmission of AIDS and chronic physical and emotional disabilites associated with prenatal exposure to alcohol and other drugs. Traditional funding mechanisms such as the ADMS and MCH block grants have not been adequate to meet the needs of this population.

Early this year, member organizations in our Coalition pulled together a small working group to examine various proposals to enhance services for pregnant alcoholic and drug dependent women, their infants and children. We began to look very closely at the Medicaid program as a mechanism to support treatment for this population of women and their children. We felt that it was appropriate to look to the

Medicaid program because it is our nation's health insurance program for poor pregnant women and their young children.

Our small working group collaborated closely with the Ad Hoc Coalition on National Alcohol and Drug Abuse Issues (a coalition of the major national organizations working on alcohol and drug issues). The working group set out to assess the current reimbursement policy for alcohol and other drug abuse treatment services under Medicaid, to develop recommendations for regulatory and legislative changes to improve Medicaid coverage and to advocate for such changes.

To assist in understanding the scope of Medicaid reimbursement for alcohol and other drug abuse treatment services under Medicaid, the group developed a questionnaire that was distributed to the State Alcohol and Drug Abuse Agencies, State Medicaid Agencies and several treatment providers in the States of California, Florida, Illinois, Kansas, Massachussetts, Michigan, New York, Pennsylvania, Texas, Utah and Washington (a list of the questions asked in the survey are attached).

We found that each state has a distinct set of alcoholism and drug addictions treatment services which are funded by Medicaid. In almost all cases, some form of detoxification, methadone maintenance and some outpatient services are reimburseable (also see attached memo from HCFA to State Medicaid Directors). Most states do not have special provisions for Medicaid reimbursement for alcoholism and drug addictions treatment for pregnant women. Michigan is working to expand Medicaid coverage to reimburse intensive outpatient services and to include room and board for pregnant women receiving intensive outpatient services. The state of Pennsylvania has enacted legislation to allow "for a continuum of alcohol and drug detoxification and rehabilitiation services." Its act specifically covers non-hospital based detoxification and residential services. However, Pennsylvania and other progressive states are forced to proceed solely with state funds.

A profound gap in reimbursement under Medicaid is for the financing of comprehensive residential services for pregnant and postpartum addicted women, their infants and children. The Institution for Mental Diseases (IMD) exclusion is the most formidable barrier standing in the way of reimbursement for this critical service. HCFA defines alcoholism and drug addictions as mental diseases and limits reimbursement for services in residential programs for mental diseases to facilities with less than 16 beds. Most residential programs for alcoholism and drug treatment have an average of 20 beds. Programs serving women, infants and children may need to be designed to serve up to 40 women if large families are to be treated under the same roof.

Comprehensive residential services are vitally important for this population for a number of reasons. To begin, in many cases pregnant women entering treatment need a range of services including prenatal care, addictions treatment, housing and employment assistance and childcare. Services are fragmented and it is very difficult for women with little or no money to take their children across town in order to get the care they need. Many of the pregnant women in need of services are addicted to more than one drug, have been addicted for a long period of time and are going to need longterm habilitation before treatment will be successful. This type of treatment is not likely to be successful on an outpatient basis or through a limited 21 -28 residential treatment stay. Studies indicate that treatment outcome improves in direct relation to the intensity and length of treatment provided. Finally, most of the women who will utilize residential services live in drug-infested neighborhoods. Their homes and comunities are not safe. They need a drug free environment and the support of other women in recovery to stay drug free and build their lives.

Our working group developed a proposal to enhance Medicaid to support residential treatment services (a summary of our proposal and a list of organizations supporting this proposal is attached). This type of treatment is the most critical component of comprehensive care for pregnant and postpartum addicted women and their children. The proposal was developed after consultation with state alcohol and drug abuse directors, state medicaid directors, local treatment programs and national organizations. While all of these groups do not support a Medicaid mandate, the final proposal we developed creates a mandate for Medicaid reimbursement for comprehensive residential services for pregnant and postpartum alcoholic and drug dependent women, their infants and children and other primary caretakers up to 12 months postpartum. It amends the definition of services available to pregnant women under the current Medicaid statute.

Most of our proposal is embodied in the Medicaid Family Care Act, H.R. 5536 and its companion bill S. 3002. These proposals would allow, at a state's option, Medicaid to cover comprehensive services to pregnant women, their children, and a caretaker parent of those children. Under a state-approved plan, providers would be required to provide comprehensive treatment services to pregnant women and their children including:

- Alcoholism and drug addiction counseling and family counseling, education and treatment, including opportunities for involvement in Alcoholics Anonymous or Narcotics Anonymous as well as parenting skills training and HIV prevention and education, all pursuant to an individualized treatment plan;
- Room and board in a structured environment with 24 hour supervision, as well as therapeutic childcare, where appropriate;
- Assistance for parents in obtaining developmental services for pre-school children, access to public education for school aged children, and public education for parents who have not completed high school;
- Assistance to families in obtaining access to health and social services, including outpatient pediatric services and well-baby care;
- Planning and counseling to assist mothers in their reentry into society, including referrals to appropriate education and vocational programs, outpatient treatment and counseling, transitional housing and assistance in obtaining affordable housing and employment upon discharge; and
- Continuing training for treatment staff.

The Congressional Budget Office (CBO) has estimated that the total cost of S. 3002 will be $17 million for fiscal year 1991 and that the total five year outlay for the years 1991 - 1995 will be $542 million. There are some differences in eligibility requirements in the House and Senate bills and cost estimates are not currently available for H.R. 5536. We are concerned that some of the cost estimates prepared by the CBO are based on unreasonable assumptions. In our view, the cost of expensive hospital based rehabilitation programs is used as one standard for determining costs. This standard needlessly drives up the cost of the benefit. In our survey of the few comprehensive residential treatment programs for women and children, we have found that the daily cost of care per family ranges from $75 to $90 per day. These costs pale in comparison to the long-term costs of maternal alcohol and drug problems on our society.

I heard Dr. Wilensky testify on Monday and I appreciate her acknowledgement of the seriousness of maternal drug addiction. She stated that HCFA will be establishing a small demonstration which will include a reconsideration of the IMD exclusion. While we applaud HCFA's concerns about these issues, we have serious reservations about a demonstration project. There is a crisis in maternal and child health care related to drug addiction in this nation. States are enacting legislation which amends child abuse statutes to include drug use during pregnancy as child abuse. Poor women and women of color are being treated as criminals in some states because they are addicted to drugs while pregnant. We can hardly afford to respond to this crisis through a modest demonstration project.

Mr. Chairman, we have been working for years to enhance Medicaid to pay for alcoholism and drug addictions treatment. The National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the Health Care Financing Administration (HCFA) conducted a demonstration project in the early 1980's which looked at the impact of using Medicaid and Medicare funding to support a continuum of care in freestanding programs. While a final report was never issued on the impact of this demonstration, the interim report issued in 1986 indicates that Medicaid reimbursement for freestanding programs is viable and is cost effective.

We can make progress in our efforts to intervene and treat alcoholic and drug dependent women when they are pregnant if we provide them with services which are comprehensive and sensitive to their experience. The time when a woman is pregnant provides an ideal opportunity for intervention. A "treatment slot" is not what we are proposing. We do not need more mediocre services for this impoverished group of women and their children. We need comprehensive programs that will give them the chance to recover and take care of themselves and their families. We view this proposal as complementary to the major and important pieces of legislation introduced by members of this Subcommittee to reduce the problems of infant mortality in this nation.

This nation has been engaged in a "War on Drugs" for a number of years. The fact that we have yet to develop a basic and humane system of addictions treatment for individuals who have no money to pay for services reflects the utter and dismal failure of this war. For pregnant women and their children, the stakes are high. Even women who are ready and motivated to seek treatment have few and often no options. It is no wonder that we have crisis on our hands.

Mr. Chairman, thank you for the opportunity to testify before you today and your steadfast leadership on these issues. We stand ready to work closely with you to improve the quality of health care services for alcoholic and drug dependent women and their families.

EXPLANATION OF MEDICAID FAMILY CARE ACT PROVIDING MEDICAID COVERAGE FOR ALCOHOLISM AND DRUG DEPENDENCY RESIDENTIAL TREATMENT

Section 1 adds alcoholism and drug dependency residential treatment services to the list of services a state must cover for Medicaid-eligible pregnant women.

Section 2 clarifies that alcoholism and drug dependency treatment services must be covered for certain Medicaid-eligible pregnant women (those with family incomes at or below 133% of poverty who are not eligible under another section- such as being an AFDC recipient) as services for conditions which complicate pregnancy. It also exempts residents of treatment facilities (as defined in #6) from the "institution for mental diseases" ("IMD") exclusion.

Section 3 adds alcoholism and drug dependency treatment services as an optional service for Medicaid-eligible caretaker relatives who are not pregnant. Most commonly, this will be a mother with dependent children. This section also exempts this service from the "comparability" requirements so that a state choosing to provide this service to caretaker relatives would not have to provide it to all other Medicaid eligibles.
It also exempts residents of treatment facilities (as defined in #6) from the "institution for mental diseases" ("IMD") exclusion.

Section 4 corrects a technical problem for pregnant women who are Medicaid-eligible only due to their pregnancy and limited income (as opposed to being eligible as an AFDC recipient). Under current law, these women lose their Medicaid eligibility 2 to 3 months after the end of their pregnancy. This section would extend their eligibility to 12 months following the end of their pregnancy. Services covered during this period would continue to be limited to "pregnancy related and postpartum" services which includes alcoholism and drug dependency treatment services. The purpose of extending eligibility is to allow a pregnant woman who enters treatment late in her pregnancy to complete treatment.

Section 5 merely adds alcoholism and drug dependency treatment services to the laundry list of Medicaid services.

Section 6 has three main parts. The first part of section 6 sets out the various services that must be provided by an alcoholism and drug dependency residential treatment facility. It also limits Medicaid coverage to non-profit non-hospital facilities with no greater than 40 beds.

The second part of section 6 requires facilities wishing to get Medicaid reimbursement to be certified by the Alcohol and Drug Abuse Single State Agency as being able to provide the full range of services required. The purpose of this requirement is to help ensure quality of care by having treatment facilities reviewed by the state agency with greatest expertise in alcohol and drug treatment.

The third part of section 6 precludes states from imposing arbitrary restrictions on duration of coverage shorter than 12 months. It does allow states to use prior authorization and utilization review to guard against inappropriate or excessive utilization of residential treatment.

Section 7 requires states to pay residential treatment facilities 100% of their reasonable costs in order to help ensure adequate levels of quality and provider participation. This section uses the provision added by OBRA '89 which currently applies to community and rural health centers.

Section 8 establishes an effective date for these provisions of July 1, 1991, regardless of whether HCFA has promulgated regulations. This date was chosen to correspond with the start of many states' fiscal year and to give adequate lead time to HCFA and the states to set up the administrative structures necessary to carry out these provisions.

MEDICAID FAMILY CARE ACT

PROVIDING MEDICAID COVERAGE OF ALCOHOLISM AND DRUG DEPENDENCY RESIDENTIAL TREATMENT SERVICES FOR PREGNANT WOMEN AND SPECIFIED CARETAKER RELATIVES

PROPOSED LEGISLATIVE LANGUAGE

1. Mandatory coverage of residential treatment for all Medicaid-eligible pregnant women.

Amend section 1902(a)(10)(A) of the Social Security Act [42 USC 1396a(a)(10)(A)] by inserting (portion underlined):

> "For making medical assistance available, including at least the care and services listed in paragraphs (1) through (5), (17) and (21) of section 1905(a) (and in the case of pregnant women receiving medical assistance under subparts (A)(i), (A)(ii) and (C) of this subsection and pregnant women described in section 1902(l), the services listed in paragraph (23) of section 1905(a)).

2. Mandatory coverage of treatment for pregnant women eligible under the 133% of poverty category.

Amend 1902(a)(10)(E) of the Social Security Act [42 USC 1396a(a)(10)] by inserting [portion underlined]:

> "(VII) the medical assistance made available to an individual described in subsection (l)(1)(A) who is eligible for medical assistance only because of subparagraph (A)(i)(IV) or (A)(ii)(IX) shall be limited to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions which may complicate pregnancy including services to treat alcoholism or drug dependency which, notwithstanding the exclusion from coverage for individuals in institutions for mental diseases contained in section 1905(a), shall include alcoholism and drug dependency residential treatment services (as defined in section 1905(t))."

3. Optional coverage of residential treatment for specified caretaker relatives.

Amend 1902(a)(10) [42 USC 1396a(a)(10)] by adding at the end of the sentence following subpart (E):

> "(XI) the medical assistance made available to individuals who are specified relatives as set forth in section 1905(a)(ii) and eligible for medical assistance under subparts (A)(i)(I),(III),(V) or (ii)(I),(II),(III) or (C) of this section, may include alcoholism and drug dependency residential treatment services (as defined in section 1905(t)) notwithstanding the exclusion from coverage for individuals in institutions for mental diseases contained in section 1905(a), without making these services available to other groups covered by the state plan notwithstanding subpart (B) of this subsection."

4. Continuation of eligibility for 12 months following end of pregnancy.

Amend 1902(e) [42 USC 1396a(e)] by inserting [portion underlined]:

> "(5) A woman who, while pregnant, is eligible for, has applied for, and has received medical assistance under the State plan, shall continue to be eligible under the plan, as though she were pregnant, for all pregnancy-related and postpartum medical assistance under the plan, including services for the treatment of alcoholism and drug dependency for a period of 12 months beginning on the first day of the month following the month in which her pregnancy ends."

Amend 1902(l)(1) [42 USC 1396a(l)(1)] by inserting [portion underlined]:

> "(A) women during pregnancy (and during the 12 month period beginning on the first day of the month following the month in which her pregnancy ends).

5. Listing of residential treatment services.

Amend 1905(a) [42 USC 1396d(a)] by adding subpart (23) as follows:

> "(23) alcoholism and drug dependency residential treatment services (as defined in subsection (t) of this section);"

6. Definition and requirements of residential treatment services.

Amend 1905 [42 USC 1396d] by adding subsection (t) as follows:

> "(t)(1) The term 'alcoholism and drug dependency residential treatment services' shall at a minimum include the following services provided either directly or by contract by a non-profit residential treatment facility that is not licensed as a hospital and has no greater than forty beds :
>
> (A) addiction education and treatment services based upon individualized treatment plans;
> (B) individual, group and family counseling;
> (C) opportunity for involvement in Alcoholics Anonymous, Narcotics Anonymous and other support groups;
> (D) for pregnant women, access and referral to prenatal and postpartum health care and family planning services, including where appropriate services provided under Title V of this act (Maternal and Child Health Services Block Grant) and services and nutritional supplements provided under [need cite here] (Women, Infants and Children Program);
> (E) room and board for parents and their children (up to age 13), subject to reasonable limitations imposed by the service provider on the number of the children, in a structured, supervised and developmentally appropriate environment;
> (F) for parents, parenting skills training and other family support services;
> (G) domestic violence and sexual abuse counseling where appropriate;
> (H) access to developmental services for pre-school children and public education for school-aged children and parents who have not completed high school including assistance to parents in enrolling their children in school;
> (I) access and referral to literacy, vocational and other employment related counseling and training where appropriate;
> (J) child care that meets applicable standards of state and local law;
> (K) counseling for the children of persons in treatment;
> (L) access and referral to other health and social services where appropriate;
> (M) reentry counseling and activities;
> (N) discharge planning including assistance in obtaining suitable affordable housing and employment upon discharge;
> (O) referral to appropriate aftercare upon discharge; and
> (P) continuing specialized training for staff in the

special needs of residents and their children, designed to enable such staff to stay abreast of the latest and most effective treatment techniques."

"(2) A facility may not receive payment under this Title for providing alcoholism and drug dependency residential treatment services unless the agency designated by the State to administer funds received for alcoholism and drug abuse services under the Alcohol and Drug Abuse and Mental Health Services Block Grant (42 USC 300x et.seq.) has certified to the single State agency (designated pursuant to section 1902(a)(5)) that the facility is able to provide, either directly or by contract, all the services specified in subpart (1) and meets all applicable state licensure or certification requirements."

"(3) To the extent covered under this Title, alcoholism and drug dependency residential treatment services shall be covered under a state plan for such period of time as is medically necessary for each individual receiving or authorized to receive these services. Notwithstanding this requirement, a state plan may limit coverage of alcoholism and drug dependency residential treatment services to a period not less than 12 months. A state may subject alcoholism and drug dependency residential treatment services to prior authorization and utilization review requirements to ensure that services are appropriate and medically necessary."

"(4) Nothing in this subsection shall exclude other alcoholism and drug dependency treatment services from coverage under a state plan to the extent such services may otherwise be covered under this Title."

7. Payment for residential treatment services.

Section 1902(a)(13)(E) [42 USC 13961(a)(13)(E)] is amended by inserting after "for payment for services described in section 1905(a)(2)(C) under the plan" the following:

",and for payment for services described in subsection (1) of section 1905(t) under the plan,".

8. Effective date.

"Effective date- The amendments made by this section apply to payments under Title XIX of the Social Security Act beginning on July 1, 1991 without regard to whether final regulations to carry out such amendments have been promulgated by such date."

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administr

6325 Security Boulevard
Baltimore, MD 21207

AUG. 2 1990

All State Medicaid Directors:

The Medicaid program is an excellent resource in the national effort to deal with drug addiction and related problems. Because Medicaid's benefits are described in terms of specific services rather than the conditions to be treated, there are often misunderstandings as to the extent that the Medicaid program's benefits can help persons with drug addiction and related problems. I am writing to review the ways that available Medicaid benefits relate to the treatment of these conditions in order to ensure that all States are aware of these possibilities.

A number of primary care services may be used, including physicians' services, clinic services, and pharmaceuticals (e.g., methadone). Additionally, services appropriate for treating addiction may be provided (1) by home health agencies, (2) under home and community-based services waivers, and (3) as part of the EPSDT benefit constellation. A number of States have also used freedom of choice waivers or exceptions to their State plans to implement managed care programs targeted to substance abuse. Case management may be used to coordinate the needed services, and special day treatment programs may be established that combine needed therapy, counseling and other services.

Inpatient hospital benefits may be used for acute treatment of symptoms, detoxification and drug-related medical complications. Rehabilitation services may be provided in a wide variety of settings. These include outpatient programs in hospitals and clinics, and inpatient programs located in nursing facilities, psychiatric hospitals, and special units in general hospitals. Rehabilitation services may also be provided in settings that are not Medicaid participating facilities.

Although payment restrictions relating to institutions for mental diseases (IMDs) can affect some inpatient programs for treating chemical dependency, it is important to remember that these restrictions do not apply to any facility that has less than 17 beds. For this reason, it may be advantageous to set up this type program in smaller facilities, even though room and board payment would not be made unless it is a participating facility. Optional IMD benefits are also available in psychiatric facilities for individuals under age 21 and for individuals age 65 and over regardless of the size of the facility.

There are many State and local programs funded by the Office of Substance Abuse Prevention, National Institute on Drug Abuse, and Health Resources and Services Administration. You may find it worthwhile to collaborate with these programs. If your State is interested in expanding Medicaid services in the area of substance abuse treatment, we can support this effort by responding to questions as they arise in developing new programs. Please contact your HCFA Regional Office.

Sincerely,

R. Abato

Rozann Abato
Acting Director
Medicaid Bureau

SURVEY ON SELECTED STATE ALCOHOL AND DRUG ABUSE AGENCY'S MEDICAID FUNDED SERVICES - 1990

Survey Questions

1. What services for alcohol and drug dependent persons are reimbursable in your State?
   a. Are there limits on the amount, duration and scope of coverage?
   b. Are there special services for drug dependent women and/or pregnant women?
2. What relationship exists between the State Medicaid Office and the State Alcohol and Drug Abuse Office?
3. What administrative barriers exist that affect eligibility for alcohol and drug dependent persons?
4. What barriers exist for service providers for participation in and reimbursement from the Medicaid program?
5. How do you proceed with Medicaid clients?
6. What is the reimbursement methodology used and what does it fail to cover that you think is critical for the delivery of comprehensive services?

Mr. **Waxman**. Thank you very much for your excellent testimony.

I want to call on Ms. Ansak, but before I do, let me express my apologies. There is a conference meeting going on on the Clean Air Act, and Congressman Wyden and I have to attend that, but we are going to have the hearing continue. We will receive the testimony—I will have a chance to review the testimony, and I apologize I won't be here to listen to the testimony.

And I would like to turn over the Chair to our colleague, Congressman Towns. We will return as soon as we can.

Ms. Ansak, I would like to call on you now.

STATEMENT OF MARIE-LOUISE ANSAK

Ms. **Ansak**. Thank you, Mr. Chairman. Thank you, members of the committee, for inviting me to this meeting.

Mr. **Waxman**. Before you start, I want to indicate Mr. Nielson and some of the other members are also going to be over at that conference, so please be understanding. We will get the testimony and have a chance to review it.

Ms. **Ansak**. We want to update the committee on the progress of the replication, and discuss problems as well as prospective improvement which we believe require legislative solution.

The On Lok model program in San Francisco was authorized in 1983 as a unique, long-term care waiver demonstration. It targets the frail, nursing home-certified elderly; provides comprehensive medical, therapeutic, and social services; and assumes financial risk by accepting capitation funding from Medicare, Medicaid and the private individual.

Distinguishing us from the social-HMO and the case management model of care are that we serve exclusively the nursing home-certified elderly; provide all services, acute and long term, without benefit limitations; consolidate case management functions with direct service delivery; and assume full financial risk.

With the On Lok model, we have successfully provided quality care to over 700 elderly, reduced their hospital and nursing home utilization, and passed a 10- to 15-percent cost savings on to the public.

In 1987, with support from Congress and private foundations, we began replicating the model. To date, 10 sites have been identified. Two are operating under waivers and capitation. Three more will begin operation by the end of this year. The rest will become operational in 1991–92.

At this point, there are four major problems or issues confronting the replication.

Issue one: The PACE sites need a longer developmental period and a more progressive approach towards assumption of full risk.

Current legislation allows for only 3 years of waiver demonstration, after which the sites assume full risk. However, our experience has suggested that more time is needed to enable the sites to develop experience and expertise to care for the frail elderly and to operate efficiently within the constraint of the capitation. To push the sites towards assuming full risk prematurely might result in significant financial loss and possible termination of the demonstration.

Therefore, we propose: Progressive assumption of risk for future sites in which a site should have the option to begin replication by assuming risk for long-term care services only with Medicaid capitation. Within 1 to 2 years, the site would then assume risk under both Medicare and Medicaid as specified by current law.

The proposed change does not change the model nor the original intent of the legislation. It also does not increase the cost of the demonstration.

Issue two: Debate on the evaluation design between HCFA and OMB has delayed waiver approval resulting in the loss of time and money by PACE sites.

We have always advocated appropriate evaluation of the demonstration. But we did not anticipate that debate on the evaluation design would significantly delay waiver approval. The problem has apparently been resolved. If the delay had been any longer, two of the five startup sites would have had to terminate for financial reasons.

Because of our continuing concern with appropriate development of the sites as well as the evaluation, we would appreciate formal specific authorization for On Lok to monitor and evaluate sites on a continuous and compensable basis. The purpose of this authority would be to assure PACE sites' continuing compliance with the essence of the model and timely detection and correction of problems.

Again, this would be part of the ongoing demonstration process not in lieu of appropriate third-party overall research and evaluation activities.

Issue three: The enactment of the Spousal Impoverishment Provision of the Medicare Catastrophic Coverage Act of 1988 has created an incentive for nursing home placement.

This provision was not specifically extended to On Lok and the PACE sites. Currently, an older person and his spouse must both become impoverished if he chooses to enroll at On Lok or the PACE sites. However, if he chooses nursing home placement, his spouse is protected. Such a disincentive undermines the model and Congress' intent to develop community-based alternatives.

Therefore, we propose, one, the Spousal Impoverishment Provision be specifically extended to On Lok and all PACE sites; and, two, changes in Medicaid income eligibility should not create disincentives for the elderly to participate in the model.

Issue four: There is considerable interest among potential sites throughout the Nation in replicating the On Lok model, but the number of waivers is now limited to a maximum of 10.

As an indication of this interest, California has already enacted legislation to replicate the model at five sites in that State alone.

We believe that it would be infeasible to make the waivers available to all prospective sites at this time because of shortage of technical assistance. We do believe the increased demand could be met prudently by an increase in the number of authorized sites from 10 to 15. Of course, Mr. Chairman, expanded discussion of my remark is included in our full statement.

In conclusion, long-term care has continued to be a key unresolved issue on the public policy agenda. In the quest for a solution to our Nation's long-term care problem, we wish to offer our contributions. I want to thank you again on behalf of On Lok, the PACE sites and the frail elderly and their families for your continued sympathetic interest and support.

[Testimony resumes on p. 365.]

[The prepared statement and attachment of Ms. Ansak follow:]

ON LOK
SENIOR HEALTH SERVICES
BAHAY PAGASA
CENTRO DI SALUTE PER GLI ANZIANI
安樂居

**Statement of Marie-Louise Ansak,
Executive Director, On Lok, Inc.
for the "Panel on Managed Care"**

**United States House of Representatives
Subcommittee on Health and the Environment
Hearing, September 14, 1990: "Panel on Managed Care"**

Introduction

Since 1983, On Lok of San Francisco, California has operated successfully as a waiver demonstration program under Federal law. With capitation funding from Medicare, Medicaid and the private individual, the program provides comprehensive medical and social services to a very frail, nursing home certified elderly population. In 1985, having evaluated On Lok's service and cost effectiveness, Congress made On Lok's demonstration a permanent program, allowing its waivers to remain in effect so long as the program operates successfully. In 1986, Congress passed legislation (P.L. 99-509) authorizing up to ten public or non-profit, community-based organizations to replicate the On Lok model under similar waivers and capitation.

This statement updates the progress of the replication effort and discusses problems and potential solutions encountered during the replication process.

The On Lok Model

The On Lok model represents a unique, consolidated approach to the delivery and financing of long-term care. Six basic principles underlie the model:

1. It focuses on the very impaired and frail elderly who have few alternatives to permanent institutional care.

2. It emphasizes and maximizes independence and continued residence in the community.

3. It provides through a single organization, comprehensive medical, restorative, social, and supportive services. The services provided range from meals, transportation, and in-home personal care, to hospital and nursing home care.

4. These services are provided or managed by a multidisciplinary team of nurses, social workers, physicians, therapists, and para-professionals.

5. Monthly capitation payments from Medicare, Medicaid and private individuals are integrated into a single pool, removing all traditional payment restrictions, such as otherwise non-reimbursable services like meals, transportation, preventive care, and frequent therapeutic care.

6. As an incentive to increase the program's efficiency and effectiveness, the provider organization assumes financial risk for all short- and long-term care without any service limitations.

The On Lok model is neither a case management system nor a Social/HMO. In contrast to a case management system where case management functions and service delivery are segregated, the model consolidates assessment, treatment planning, direct service provision, and progress monitoring. And in contrast to a Social/HMO which serves all elderly age 65 and older, the model serves exclusively the frail. Its financial viability does not depend on spreading of risk among healthy and frail elderly participants. Rather, it depends on the experience and expertise of the multidisciplinary team which provides and manages the care of its participants.

By consolidating service delivery, integrating funding, and instituting provider assumption of risk, the multidisciplinary team must keep quality of care high while controlling program costs. By preserving or enhancing the elderly's health and independence, the team minimizes the use of hospital and nursing home care. Providing low cost services in the least restrictive setting (the day health center or home) maximizes the participant's quality of life while decreasing the use of high cost services. Although On Lok's participants are frail, have been certified as eligible for nursing home care, and often have significant disabilities, their hospital utilization is only 70 percent of the national average for the general 65+ population who are undoubtedly healthier and more independent. On Lok's nursing home utilization is also low: only approximately 5 percent are placed in a nursing home. The resulting savings are used to cover otherwise non-reimbursable services described above. (For further details of how the On Lok model operates, please refer to the attached document)

The efficiency and effectiveness of the On Lok model is translated into solid cost savings for Medicare and Medicaid. Not only did the waiver demonstration use no new public dollars, it was estimated that On Lok's Medicare/Medicaid capitation was 10 to 15 percent below the costs that would have been incurred by a similarly frail population using the traditional fee-for-service system.

The PACE project

The success of the model, the interest of providers, and the support of Congress prompted enactment of PL99-509 in 1986 to replicate the model at ten sites nationwide. In 1987, On Lok launched the Program for All-inclusive Care for the Elderly (PACE) to identify potential sites, provide technical assistance, and manage the replication process.

The PACE project is unique in many ways. First, unlike past national demonstrations, the PACE sites have more than a blue print to guide their development. They have an operating program to serve as a model as well as to provide technical assistance. Successful sites will serve as models and technical assistants to yet other sites in the future. Second, because sites must complete their development before starting the waiver demonstration, the chance of a successful demonstration is enhanced. The third feature is that funding for the development of the sites is primarily from private foundations and the sites themselves. And, since the Medicare/Medicaid capitation payments are based on current fee-for-service spending, no new public dollars are needed to cover the demonstration's benefit cost.

Start-up funding for sites and for On Lok's technical assistance has been provided by a consortium of foundations: Robert Wood Johnson Foundation, John Hartford Foundation, Retirement Research Foundation, Public Welfare Foundation, Colorado Trust, and many others.

Following is a summary of progress to date:

1. Ten sites have been identified and are actively replicating the model. They represent providers under various organizational auspices and

operating in different Medicaid and regulatory environments. The PACE sites are:

Beth Abraham Hospital	Bronx, New York
Richland Memorial Hospital	Columbia, South Carolina
Umoja Care	Chicago, Illinois
East Boston Neighborhood Health Center	Boston, Massachusetts
Bienvivir Senior Health Services	El Paso, Texas
Community Care Organization	Milwaukee, Wisconsin
Rochester General Hospital	Rochester, New York
Total LongTerm Care	Denver, Colorado
Providence Medical Center	Portland, Oregon
Coalition for Elder Independence	Oakland, California

After three years of development, two of these sites - Providence Medical Center (OR) and East Boston Neighborhood Health Center (MA) - are operating under waivers with Medicare and Medicaid capitation and assuming financial risk. The waiver applications of three additional sites - Beth Abraham Hospital (NY), Community Care Organization (WI), and Richland Memorial Hospital (SC) - have been approved and they are expected to begin operation before the end of this year. The remaining five sites are in various stages of development and will begin operation in 1991 and 1992.

2. The replication of the On Lok model continues to generate interest among providers. Many, especially in California, have expressed their intent to proceed with the replication. In 1989, California enacted legislation authorizing its Medicaid agency to proceed with the replication of On Lok at five sites, if additional federal waivers become available.

3. A standardized approach to establishing Medicare and Medicaid capitation rates has been operationalized.

4. A risk sharing mechanism which allows sites to gradually assume financial risk but also limits any loss to Medicare and Medicaid has been developed.

5. A standardized, minimum data set has been established at each PACE site. The data will enable HCFA, the Medicaid agencies, and the evaluator to assess the performance and cost-effectiveness of the sites. It will also provide a longitudinal data base to determine the actual cost of long-term care for a significant proportion of the older population -- a major policy question.

6. An evaluation design has been developed to assess the financial viability and the cost effectiveness of the PACE sites. This design calls for tracking the utilization and costs of a comparably frail population as a control group. The data will yield valuable information on the cost of long-term care under the current Medicare and Medicaid systems.

7. A consortium structure has been established to allow On Lok, PACE sites, HCFA, and state Medicaid agencies to jointly resolve issues and problems encountered during the replication process, e.g. standard of care, middle income financing, etc.

Problems and Proposed Solutions

In the course of replication, many problems and issues were encountered. With the support of HCFA, Medicaid agencies, the foundations, and the commitment of the PACE sites, many have been resolved. However, there are four major problems or issues confronting the replication which On Lok believes, require legislative solution.

Issue One: The PACE sites need a longer developmental period and a more progressive approach towards assumption of full risk.

Current legislation allows for only three years of waiver demonstration after which the sites are to assume full risk. However, it took On Lok ten years of experimentation to develop the model. The current experience of the PACE sites also suggests that a longer development period is needed.

The reason is inherent in the On Lok model itself. To be able to care for the complex health problems of the frail elderly, to meet their needs and the family's demands equitably and to operate efficiently within the constraint of the capitation requires a multidisciplinary team with expertise and experience. Such expertise and experience can only be developed over time while the team operates in a capitated environment. On Lok and the sites have attempted to simulate this environment during the start-up phase. But often, prior to waivers, the sites lack the case management authority to do this. At this point, sites which have received their waivers are proceeding with the demonstration with a relatively new multidisciplinary team. They are very concerned about the feasibility of assuming full risk in three years.

Furthermore, all sites are community-based non-profit organizations, often with very limited assets and resources. Although the risk sharing mechanism during the demonstration period provides some margin of security and comfort, it is difficult for sites to sustain significant financial losses as a result of unexpected utilization of services, particularly acute care, and/or the inexperience of the multidisciplinary team.

Therefore, On Lok proposes:

> A progressive assumption of risk for future sites. In this approach, a site which has otherwise met all demonstration criteria under the replication provision should have the option to begin replication by accepting a Medicaid capitation only and assuming risk for only long-term care services. Within one or two years, the site would incorporate all services of the model - acute and long-term care services - and assume risk under both Medicare and Medicaid capitation as specified by the current legislation.

In this approach, there may be concern that the site might shift cost to Medicare during the initial Medicaid capitation period. However, because the sites will eventually assume full risk, the incentive to control costs and utilization of all services is kept throughout the demonstration. Cost shifting, if any, should be minimal. Additionally, careful monitoring would quickly identify any attempted cost shifting.

For this proposed change in the replication approach, there should not be any additional cost to the public. This is because throughout the replication, the sites are kept under either Medicaid capitation only or Medicare and Medicaid capitation.

Finally, the proposed change does not change the model or the original intent of the legislation. The sites are to consolidate all service delivery and to assume full risk.

Issue Two: The debate on the evaluation design between HCFA and OMB has delayed waiver approval resulting in the loss of time and money by PACE sites.

To assess the replicability of the On Lok model at the sites, a cost effectiveness evaluation is necessary. HCFA had proposed a design in which the sites performance - the quality of care and the cost competitiveness of the capitation rates - are compared to a group of comparably frail elderly using the traditional fee-for-service system. OMB initially objected to the design because it did not involve a random sampling of a demonstration group - the PACE site participants - and a control group within the site's service area..

On Lok and the PACE sites support a thorough evaluation of the model. However, a randomized sampling design would completely undermine this demonstration. First, like any capitation program, the financial viability of the On Lok model depends on enrollment. Random assignment in which an interested older person with high service need may not be served by the program for experimentation reasons would impact on enrollment. Second, the model targets only the frail elderly - a small segment (5 to 10 percent) of the elderly population. Randomization effectively reduces the eligible pool by half. Finally, all sites are community-based organizations, and depend on local support for referrals and donations. It would be difficult to secure the confidence of the community in a program which cannot guarantee service access to its needy citizens. The irony is that the financial viability is one of the questions to be addressed by the evaluation.

At this point, a research methodologist contracted by HCFA has evaluated HCFA's proposed design and has also come to the conclusion that randomization is inappropriate for this demonstration. He has also recommended various design considerations and statistical methods to correct for problems which may arise from a non-randomized design. We understand that OMB has accepted his recommendation and the demonstration can continue.

Although the problem has apparently been resolved, the point is that the appropriateness of evaluation design should not be used as a debating point to withhold approval of sites to undertake their demonstration. This debate between HCFA and OMB delayed the approval of the waivers to two initial sites for three months. Both had to rely on resources of the sponsoring organizations to continue the replication effort. If the delay had been any longer, both sites would have had to terminate the demonstration.

Because of On Lok's continuing concern with appropriate development of the sites as well as implementation of the established standardized data collection system, On Lok would appreciate:

- Formal specific authorization for On Lok to monitor and evaluate sites on a continuous and compensable basis, except when HCFA finds this to be excessively costly, duplicative of the existing evaluation process, or of poor quality. The purpose of this authority would be to assure PACE sites' continuing compliance with the essence of the model, timely detection and correction of problems (including notification of HCFA) and completeness and reliability of the standardized data set. Again, this would be part of the on-going demonstration process not in lieu of appropriate third party overall research and evaluation activities.

Issue Three: The enactment of the Spousal Impoverishment Provision of the Medicare Catastrophic Coverage Act of 1988 has created an incentive for nursing home placement.

A recent change in Medicaid eligibility, the Spousal Impoverishment Provision, allows the spouse of an institutionalized person to retain most of the household income and assets up to a given ceiling. This provision has also been extended to Medicaid community-based waiver programs operating under the 2176 authority. Unfortunately, it has not been specifically extended to the statute replicating the On Lok model. Without such a provision, On Lok and the PACE sites have experienced a disincentive for the elderly to enroll. For example, an older person may be Medicaid eligible (even though his community-dwelling spouse retains the couple's income and assets) if he chooses to be institutionalized. However, if he chooses to enroll at On Lok or the PACE sites, both he and his spouse must spend down, becoming impoverished before Medicaid covers the cost of his care. Such a disincentive to enroll undermines the intent of the model and Congress to develop community alternatives to nursing home care.

Therefore, On Lok proposes:

a. The Spousal Impoverishment Provision be specifically extended to On Lok and all PACE sites where the states so elect, independent of any state action with respect to other aspects of their Medicaid programs.

b. Future changes in Medicaid income eligibility should not create disincentives for the elderly to participate in the model.

The Spousal Impoverishment Provision has, to a limited extent, liberalized Medicaid eligibility and will benefit a segment of the long-term care population. Nonetheless, On Lok and the PACE sites cannot truly provide for the long-term care needs of those whose resources are above the poverty level. In the absence of Medicaid, the share-of-costs or premiums to participate at On Lok and at the PACE sites currently range from $1,200 to $2,300 monthly. Not until these people are relatively impoverished and therefore become eligible for Medicaid does the combined funding from Medicare and Medicaid to cover their health care needs become adequate. This is an obvious problem which will have to be addressed at some point in the future.

Issue Four: There is considerable interest among potential sites throughout the nation in replicating the On Lok model but the number of waivers is now limited to only a maximum of ten sites.

Since the PACE project was launched in 1987, On Lok has been approached by many committed, well-qualified health and social service organizations to replicate the model. Their concern is the urgent need of the frail elderly in their communities for a community alternative to institutional care. Medicaid agencies in California, Oregon, Hawaii, South Carolina, and Wisconsin have witnessed overcrowding of nursing homes and are eager to develop more PACE sites as a lower cost, more humane alternatives to building more nursing homes In fact, California has already enacted legislation to replicate the model at five sites in that state alone even though the ten federal waivers have already been used or targeted.

On the one hand, while it is tempting to meet this demand by making waivers generally available, it would be unwise to do so without the benefit of the evaluation of the initial PACE sites. On the other hand, considering the time needed to develop each site, limiting the demonstration to ten sites will slow the development of this model as a viable long-term care alternative.

A number of facts suggest that it would be prudent to broaden the demonstration to more sites, short of making waivers available to all. First, past evaluations of the On Lok model have suggested that it is a humane and cost effective system of care. Repeated medical and financial audits by the Medicaid agency of California have not identified major deficits or concerns. Second, since the replication, the model has come under close scrutiny by HCFA and many state Medicaid agencies. Their findings satisfy their concern for quality, cost competitiveness, and accountability. Third, On Lok and existing PACE sites are interested in maintaining the integrity of the model. They will continue to be models and technical assistants to future sites. Finally, since the demonstration is funded with capitation, it involves shifting of existing Medicare/Medicaid resources rather than new dollars. Expanding the demonstration would not result in run-away cost and programs of dubious quality.

Therefore, On Lok proposes:

> An increase in the number of authorized sites from ten to fifteen. Excluded from the authorized number would be any sites which opt to begin with Medicaid only capitation and have not begun demonstrating the full model with Medicare and Medicaid capitation.

The reason for not counting the start-up Medicaid-only sites is because the present Medicaid Section 1115 provision allows states to operate a wide variety of demonstrations, most with no resemblance to the On Lok model. However, sites which are interested in replicating the On Lok model, using the demonstration provision as their justification and which opt for a Medicaid 1115 start-up should meet all criteria and requirements specified for this replication including the current requirement of On Lok's review and recommendation.

Conclusion

Long-term care has continued to be a key unresolved issue on the public policy agenda. A number of bills, comprehensive or more limited, have been introduced in Congress. Their price tags, unfortunately, are also prohibitive. The recent repeal of the Medicare Catastrophic Coverage Act of 1988 suggests that any design of new health benefits and especially the creation of new financing mechanisms to pay for them must be approached systematically and cautiously.

In this quest for a solution to our nation's long-term care problem, On Lok wishes to offer its contributions:

1. A humane, community-based, and financially affordable alternative to our existing institutionally focused long-term care system;
2. A replication demonstration in which the utilization and cost data from the PACE sites and the comparison group will provide information for policy options and choices; and
3. A gradual approach to change our existing system through a process of building upon successful models and creatively using existing public and private resources.

In conclusion, we want to thank you again on behalf of ourselves and the frail elderly their families, for your continued sympathetic interest and support.

HISTORY OF ON LOK

In 1972, On Lok received a grant from the Administration on Aging to develop a day care center for the elderly in San Francisco's Chinatown. Building upon this foundation, the On Lok service program developed incrementally in response to the needs of the elderly in its community. In 1975, On Lok received an Administration on Aging Model Project on Aging grant to refine its existing day health center and, with the day health center as a base, to establish an outpatient continuum of care. During the four-year grant period On Lok developed expanded in-home services including portable meals, chore services and home health care as an adjunct to its day health center program. In 1978, On Lok received funding from the Office of Human Development Services to plan, develop and study a "Community Care Organization for Dependent Adults" — an extension of the continuum to include all health and health-related services for elderly certified for nursing home care. Thus, On Lok has developed into a comprehensive long-term care program, the Community Care Organization for Dependent Adults (CCODA), which differs significantly from traditional long-term care models in that:

- The full range of social and medical services are integrated into a single program.

- The same professionals (a multidisciplinary team) plan and deliver all services, either directly or through contracts.

- On Lok has total control over all service expenditures.

- On Lok emphasizes personal independence and utilizes the day health center as its primary delivery setting.

From 1979 to 1983, the CCODA operated under Federal Medicare waiver authority, and a single source (Medicare) paid for all services. At the end of this waiver period, the CCODA appeared to be a financially viable model that benefited its funders, its participants and their providers. In 1983, On Lok initiated the Risk-Based CCODA, in which the successful waiver program remained unchanged, but its funding base under Medicare and Medicaid waivers was broadened to offer fixed, competitive rates to the system's traditional payers for long-term care services. Since 1983, On Lok has received prospective monthly payments from Medicare, Medicaid and/or the individual (based on the individual's entitlement) and has assumed full responsibility for using the resulting pool of funds as needed to meet all the health and health-related needs of its 300-plus participants. With capitation financing, On Lok gained freedom from traditional (fee-for-service or diagnosis-related groups) reimbursement systems and requirements, becoming the first provider to assume full financial risk for the total health care of an impaired long-term care population (Zawadski and Eng, 1988).

PRINCIPLES OF ON LOK

The On Lok model of comprehensive risk-based long-term care, which is the prototype for the PACE programs, was developed to address the needs of long-term care clients, providers and payers. For most clients, the comprehensive service package permits them to remain at home while receiving services rather than be institutionalized. Flexible reimbursement allows providers to deliver the services clients need, rather than be limited to those reimbursable under the fee-for-service system. Finally, the model offers potential cost savings for this population, when compared with equally frail individuals living in nursing homes or receiving services in the community.

The principles underlying the On Lok model are:

- **Focus on the very impaired and frail elderly who require ongoing care for the rest of their lives.** This model targets a specific high-cost long-term care population which has few alternatives to permanent institutionalization.

- **Inclusion of comprehensive medical, restorative, social and supportive services.** The full continuum of acute and long-term care options must be available to respond appropriately to the multiple and interrelated problems of a long-term care population.

- **Service integration through consolidation.** All services must be well integrated to respond to the needs of the client in the most effective and efficient manner. A multidisciplinary team of professionals and paraprofessionals assesses each new client, develops and refines treatment plans, and is responsible for delivering services.

- Control of service delivery by team. The service team controls all services required by the impaired client population. The team can mobilize any service since fee-for-service restrictions do not apply.

- Community residence. The clients' continued residence in the community is emphasized along with the community's ongoing participation in the program.

- Integrated funding. Resources are integrated into a single fund which is drawn upon to provide services. Reimbursement is no longer tied to a particular payer (Medicare or Medicaid) and, consequently, is not subject to related payment restrictions, e.g., ordinarily Medicare would not pay for the kind of preventive care essential to avoiding costly hospitalizations for On Lok's frail elderly population.

- Provider assumption of financial risk. The organization must be able and willing to assume financial risk, that is, possess the management skills and information base to monitor clients, services and costs and readily adapt to changing situations to increase the efficiency and effectiveness of the service system.

On Lok incorporates many of the features which exist singularly in other "alternative delivery systems" including Health Maintenance Organizations (HMOs), Medicaid §2176 Home and Community Based Waiver Programs, and Social Health Maintenance Organizations (S/HMOs). For example, health maintenance organizations may offer comprehensive services to their enrollees; however, the package does not include or provides very limited long-term care services like nursing home care, in-home chore and personal care services. For Medicaid recipients, community-based long-term care services are often available through States' home and community-based waiver programs. But these services are not provided in conjunction with medical care. In many respects, On Lok is similar to the S/HMOs, specifically in the areas of financing and integrating acute and long-term care. The difference is that On Lok serves an exclusively frail population; and, consequently, On Lok's service delivery approach is distinctly different. While the S/HMO model is essentially pure case management, On Lok provides services directly.

THE ON LOK PROGRAM

Key features of the On Lok program include its target population, outreach methods, enrollment/disenrollment procedures, service coverage and consolidated service approach.

Target Population

Eligibility for On Lok is limited to individuals who meet the following criteria. Participants must:

- Be at least 55 years of age,
- Be certified, at the point of intake, by the State of California to have chronic medical conditions which require continuous care in a skilled nursing facility (SNF) or intermediate care facility (ICF) (Attachment A), and
- Reside within On Lok's geographic catchment area, which lies within the northeast section of San Francisco. Its boundaries are: Northeast — San Francisco Bay; West — Van Ness Avenue to Sutter Street; South — Sutter to Sansome; East — Market to San Francisco Bay. San Francisco zipcodes included in this area (Attachment B) are: 94109 (partial), 94133, 94111, 94108, 94104 (partial).

Table 1 shows the sociodemographic, medical, and health and functional characteristics of the On Lok population.

Table 1
SOCIODEMOGRAPHIC, HEALTH AND FUNCTIONAL STATUS CHARACTERISTICS
July through December, 1988

AGE		SEX		MARITAL STATUS		NUMBER OF CHILDREN	
(N = 338)		(N = 338)		(N = 334)		(N = 338)	
55 - 64	5%	Male	34%	Single	8%	None	34%
65 - 74	17			Married	24	One	24
75 - 84	36	Female	66	Divorced	4	Two	17
85 - 94	35			Widowed	61	Three	10
95+	7			Separated	3	Four or More	17
Mean =	81.76						

ETHNICITY		USUAL LIVING SITUATION	
(N = 338)		(N = 338)	
Chinese	84%	Home Alone	34%
Caucasian	11	Home with Others	26
Filipino	1	On Lok House	22
Italian	3	On Lok Communal Living Arrangement	12
Hispanic	<1	Inpatient Facilities	6
Black	0		
Other Asian	<1		
Other	<1		

TOTAL MONTHLY INCOME		SOURCE OF INCOME*		ELIGIBILITY	
(N = 316)		(N = 316)		(N = 338)	
$ 1 - $300	8%	SSA	70%	Medicare & Medi-Cal	74%
$301 - $400	11	SSI	75	Medicare MNO	6
$401 - $500	37	Pension	10	Medi-Care only	11
$501 - $600	36	Investment	2	Medi-Cal only	9
$601+	7	Family Support	<1		
		Other	5		
Mean =	$586	*Multiple sources cited			

MEDICAL CONDITIONS
(N = 337)

Cardiovascular	78%	Neoplasm	31%
Nervous System/Sense Organ	70	Skin Condition	13
Musculoskeletal	55	Endo/Nutri/Metabolic	25
Digestive	57	Respiratory	20
Blood/Blood Forming	46	Genitourinary	22
Mental Disorder	46	Congenital	0

FUNCTIONAL IMPAIRMENTS
(N =313)

COGNITION		CONTINENCE	
Short-Term Memory	86%	Bladder	82%
Long-Term Memory	82	Bowel	50
Orientation	61		
SENSORY		ACTIVITIES OF DAILY LIVING	
Vision	96%	Bathing	73%
Hearing	55	Grooming/Hygiene	59
Speech	31	Dressing	51
		Toileting	48
MUSCULOSKELETAL		Transferring	61
Lower Extremity	86%	Walking	56
Upper Extremity	54	Eating	18

A profile of the typical chronically impaired older person in need of long-term care shows that many interrelated problems must be managed to provide good care. The On Lok participant is most likely to be a woman over the age of 80 with several serious medical diagnoses. As a result, this client has severe functional impairments, such as memory problems, incontinence and inability to perform activities of daily living. Often this quite frail individual is widowed, lives alone and has a very limited income (frequently just SSI). Thus, unlike HMOs and S/HMOs, On Lok serves an exclusively frail population and has developed a service system specifically for their intensive needs.

Outreach

On Lok's participants are referred to the program through a network consisting of hospital discharge planners, long-term care agencies, including home health agencies, community physicians, community groups and associations, friends and family of current and former On Lok participants. Table 2 shows the referral sources for the On Lok population. On Lok has established its referral system by maintaining an active presence in its community. This presence has been developed by providing community education, undertaking joint projects with local schools and associations, maintaining an active volunteer program, encouraging attendance at On Lok's biweekly Open House, and sponsoring special events which are open to participants' families as well as the community at large.

Table 2
REFERRAL SOURCES

Referral Source	% of Current Census
Hospital	14
Other health care facility/agency	12
Social service agency	13
Individual health care professional	8
Family or friend	48
Self-referral	4
Other	2

Because On Lok targets only the very frail in a well-defined geographical area in San Francisco, standard marketing approaches adopted by HMOs including television, newspapers, billboards and so forth are not cost-effective. Rather, On Lok depends on its own staff, especially the intake coordinator and the social worker, to reach potential participants. Consequently, On Lok's expenditures for outreach are very low, approximately the cost of one staff person.

Based upon 1980 Bureau of the Census data, 13,391 persons aged 65 and over reside in On Lok's three and one-half square mile service area. This figure represents 18 percent of the total population, a relatively high concentration of elderly persons. It is estimated that the number of elderly eligible for On Lok's program is approximately 1,000 (7.5 percent of 13,391).* With an average census of 305, at any given time On Lok is serving at least 30 percent of the potential population in its catchment area.

Enrollment/Disenrollment

Once a potential participant is referred to On Lok, the intake coordinator conducts an initial screening in the home to determine if the individual is an appropriate referral. If the individual does not meet certain criteria, for example he/she is less than 55 years of age or lives outside On Lok's catchment area, he/she is referred to more appropriate providers. If the individual "passes" the initial screening, a complete intake and assessment is conducted by members of On Lok's multidisciplinary team, that is, the physician, nurse, social worker, physical therapist, occupational therapist and dietician. A treatment plan is also developed during this assessment.

The assessment and treatment planning information is forwarded to the State of California's Department of Health Services for review. If the State certifies that the potential participant meets the State's Medicaid criteria for either skilled nursing or intermediate levels of care, the potential participant is eligible to enroll in On Lok. Participants' nursing home eligibility is never recertified by the State, creating an incentive for the program to improve the participants' functional level to the greatest extent possible.

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* While data on the health status of these individuals is unavailable, estimates can be made on the basis of other studies. The number of individuals likely to be eligible for the On Lok program is estimated to lie somewhere between the 12-17 percent who are likely to be bedridden or require assistance in activities of daily living (Morris and Yonket, 1981), and the 5 percent who are estimated to use nursing home services (Chartbook on Aging in America, 1981).

A requirement for enrolling in the On Lok program is that the participant accept On Lok as sole service provider. For some, this means giving up a primary care physician whom he/she has visited for years; in fact, as an On Lok participant, all Medicare and Medicaid benefits in the fee-for-service sector are suspended.

If an individual is dissatisfied with the care On Lok provides, he/she is always free to disenroll from the program. On Lok is responsible for reinstating traditional Medicare and Medicaid benefits immediately upon disenrollment. Actually, there have been few voluntary disenrollments due to participant dissatisfaction with the program. The vast majority of participants remain enrolled in the program until their death, with deaths accounting for 90 percent of all disenrollments. Of the remaining disenrollments, most are due to participants moving out of On Lok's catchment area. For example, during the six-month period of July through December, 1988, 32 participants left the program. Of the 32, 30 died, one moved outside of On Lok's geographic catchment area and one disenrolled voluntarily.

During the same six-month period, 33 new participants were enrolled. Obviously, census building is a constant priority as approximately 10 percent of On Lok's average census of 305 must be "replaced" every six months. In other words, a minimum of five new participants must enroll in the program each month to maintain program census.

Service Coverage

On Lok provides a comprehensive service package including all health and social services, both inpatient and outpatient, required by its frail elderly population. There are no limitations on service coverage, and the range of services is much broader than traditional Medicare and Medicaid benefits. For example, On Lok is free to provide home repairs and chore services if they are necessary to maintain independence successfully in the community.

On Lok delivers the majority of outpatient services directly and contracts for inpatient hospital and nursing home care. Refer to Table 3 for a list of available services and method of delivery, either staff or contract. The reliance on On Lok's own staff to deliver day-to-day services stems from the belief that direct delivery enhances On Lok's ability to insure both continuity and quality of care. For medical specialty and inpatient services, On Lok contracts with local providers and specifies that contractors must work closely with On Lok staff. For example, On Lok's home health nurse visits participants in the nursing home on a weekly basis to monitor their care.

On Lok's multidisciplinary team assesses each participant's need for adult day health care, medical and in-home services. The team develops a treatment plan for each participant based upon his/her individual needs and is unrestricted *apriori* as to the number or amount of services which can be allocated to an individual.

Table 3
SERVICES BY PROVIDER ARRANGEMENT

SERVICE	PROVIDED BY	SERVICE	PROVIDED BY
ADULT DAY HEALTH CARE SERVICES		MEDICAL CARE	
Transportation	Staff	Primary Care	Staff
Social Services	Staff	Audiology	Contract
Nutrition Counseling and Meals	Staff	Dentistry	Contract
Nursing	Staff	Optometry	Contract
Restorative Therapy	Staff	Podiatry	Contract
Recreation Therapy	Staff	Speech Therapy	Contract
Personal Care	Staff	Outpatient Specialists	Contract
		Drugs	Contract
IN-HOME SERVICES		X-rays	Contract
Home Health Care	Staff	Laboratory	Contract
In-Home Personal Care/Chore Services	Staff		
Home-Delivered Meals	Staff	INPATIENT SERVICES	
		Inpatient - Med/Surg	Contract
		Inpatient - ICU/CCU	Contract
		Inpatient Specialists	Contract
		Ambulance	Contract
		Emergency Room	Contract
		Nursing Home	Contract

On Lok operates 24 hours each day, 365 days each year. Most services are received in one of On Lok's three adult day health care centers. A participant's attendance schedule depends on need for professional care, supportive services and socialization. For individuals not scheduled to attend a center, home services (meals, nursing care, personal care) are available and are provided as needed. Some individuals also receive overnight attendants. Finally, if necessary, participants are referred to specialists, nursing homes or hospitals.

On Lok integrates its health care delivery system with community housing projects including two run by its affiliates: a HUD 202 Section 8 housing project operated by On Lok House, Inc. and a recently opened SRO-type residence operated by On Lok Community Housing, Inc. While housing is not a formal component of the On Lok model, insuring that participants have adequate shelter is important to maintaining them successfully in the community. Approximately one-third of On Lok's participants reside in housing sponsored by one of On Lok's corporations.

Consolidated Service Approach

In contrast to traditional case management, On Lok adopts a consolidated approach to service delivery. In a brokerage system of case management (Zawadski and Eng, 1988), a professional team consisting of a social worker, nurse and/or physician assesses a participant's needs and develops a treatment plan. Then either a member of the team or a separate case manager is designated to arrange for delivery of services which may be delivered by yet other providers. All these functions are consolidated in the On Lok multidisciplinary team.

Every service, including those provided by contracted providers, is controlled by the multidisciplinary team, which has the dual responsibility for maintaining a high quality of care and controlling program costs. The team is charged with assessing participant needs, formulating care plans, directly delivering services and providing ongoing monitoring of treatment results. Ongoing monitoring often uncovers the need to adjust the care plan.

On Lok's multidisciplinary team is composed of professional and para-professional staff:

- Physician
- Nurse Practitioner
- Nurses - RN and LVN
- Occupational Therapist
- Physical Therapist
- Dietician
- Day Health Center Supervisor
- Recreation Therapist
- Social Workers
- Health Workers
- Drivers

Service Strategy. The multidisciplinary team's strategy is to maintain or improve the health and independence of participants so that the need for high cost, more restrictive services like hospital and nursing home care, can be postponed or reduced. The key elements of this strategy are:

1. **Preventive Care.** Methods used to reduce acute episodes include intensive monitoring and tracking of participants' medical and social conditions such as blood pressure, nutritional intake and medication compliance, and anticipation of risks like falls, skin breakdown and psychosocial problems.

2. **Rehabilitation.** Through education and re-training in mobility and activities of daily living, participants' functional capacity and degree of independence are strengthened and stabilized, thereby reducing the need for supervision and assistive support.

3. **Substitution of Services.** The use of low cost services in the least restrictive setting (day health center or participant home) provides community-based options which maximize participant quality of life and reduce the use of high cost services.

Assessment and Treatment Planning Process. On Lok participants are assessed quarterly by the multidisciplinary team and are monitored daily so that services can be allocated in response to their changing needs. A system of formal and informal mechanisms exists to assess a participant's condition, identify changes and to communicate these changes to key members of the team. Three formal meetings are convened regularly:

1. **Quarterly Intake and Assessment Meeting.** Each new enrollee, prior to enrollment, receives a comprehensive assessment by each professional member of the multidisciplinary team, who also develops a treatment plan. Upon completion of these individual professional assessments, an Intake and Assessment meeting is convened where the social, health and functional statuses of the potential participant are discussed; the team reaches consensus on a multidisciplinary treatment plan; and an implementation strategy is developed. Subsequently, a conference is held with the applicant and/or family members to discuss the treatment plan. If the applicant agrees to comply with this plan, he/she is enrolled in the program and service delivery commences. Once a participant is enrolled in On Lok's program, a formal reassessment is conducted routinely every three months.

2. **Daily Meeting.** The team meets daily to briefly discuss the progress of participants scheduled to attend the day health center that day. This meeting alerts team members to changes in participants' conditions and treatment results. Based on the health conditions of the participants and their prognosis, services are added, reduced or withdrawn to maximize independence and safety or to reduce the likelihood of incurring high cost services.

3. **Special Intake and Assessment Meeting.** Whenever a participant suddenly experiences significant changes in health status (for example, suffers a stroke or requires an unanticipated hospitalization) or in social environment (for example, is evicted or loses an informal caregiver through death or illness) a special meeting is convened. Rather than wait for the routinely scheduled quarterly assessment, the participant is immediately re-assessed and a new plan is developed.

Together, these mechanisms allow participant information to be shared by all team members, and service resources to be allocated in the most timely and efficient manner.

Service Allocation Decisions. The team's approach to service allocation is intended to manage the risks inherent in maintaining frail elderly in the community within On Lok's resource limitations. The team's options in allocating services are to add/reduce services and to alter the type of services provided (e.g., adult day health care versus home care). Some of the major routine and episodic service allocation decisions made during the Intake and Assessment meetings include:

- Number of days per week of day health center attendance,
- Type and volume of services provided in the home,
- Use of extensive restorative versus maintenance rehabilitation services,
- Need for alternative housing, intensive home health or nursing home care,
- Need to add, reduce or discontinue services as a means to maximize participant independence,
- Allocation of services during acute hospitalizations, and
- Plan for service needs in anticipation of participant's discharge from inpatient facilities (acute hospital or nursing home).

In the allocation of services, the multidisciplinary team concurrently evaluates key participant-related factors and organization-related factors. The participant-related factors particularly important in determining a participant's "at risk" status and need for services are:

- Stability of participant's condition: Specifically, the medical status of individuals who are susceptible to falls and weight gain (e.g., congestive heart failure or diabetes), or who have recently been discharged from an inpatient facility.

- Manageability of a participant within the program: For example, threats posed by wandering or behavioral outbursts.

- Caring capacity of participant and caretakers: The extent to which a participant and his/her informal supports can provide care given the participant's functional condition and manageability.

Once a participant's "at risk" status and service needs have been defined, the team adddresses On Lok's carrying capacity in light of overall resources and constraints. The program has three limitations:

- Physical space: The licensed capacity of On Lok's three adult day health centers restricts the maximum daily attendance as well as total census.

- Personnel: Staffing for each of the program's service departments places a ceiling on service availability.

- Vendors: The availability of contract services, particularly nursing home beds, restricts the number of participants who may be institutionalized concurrently.

During the multidisciplinary team's assessment process, the needs of each participant are assessed relative to other participants and the program's total resources. With this information, the team begins negotiating a participant's treatment plan: balancing the participant's medical condition, level of functional impairment, health wishes and definition of quality of life, the family's preferences and the consequences of allocating or not allocating particular services. The resulting treatment plan reflects team consensus, and participant and/or family approval.

Control and Flexibility. Because the multidisciplinary team directly provides most services, controls access to others, and is not limited by coverage constraints in the fee-for-service system, it may tailor specific services or service programs to individuals. For example, On Lok has created a specialized program to reduce hospital utilization. Certain individuals receive short-term intensive medical monitoring rather than placement in the hospital for observation or convalescence for such common medical conditions as mild respiratory or urinary tract infections, vertigo, unsteady gait due to medications, hydration needs and post-operative hip fracture recovery. Participants assigned to this program attend the day health center seven days a week and receive night supervision through On Lok's home care staff, usually in On Lok's transitional housing unit because their own homes are not appropriate for overnight attendant care (for example, too small). Authorized by the multidisciplinary team, this program has become an important component of On

Lok's preventive care system, significantly reducing the numbers of admissions and lengths of stay in hospitals.

UTILIZATION PATTERNS AND COST ALLOCATION

On Lok's objective is to minimize participants' need for high cost, restrictive inpatient services by providing services in the adult day health care center. Table 4 presents On Lok's utilization information for the period July 1, 1988, through December 31, 1988. Of particular significance are the high proportion of participants who receive professional services each month, the intensity of these services and the low utilization of inpatient services.

Table 4
SERVICE UTILIZATION SUMMARY
July 1, 1988 - December 31, 1988
(n = 335)

	Total No. of Service Days for Period	Proportion Receiving Services (%)	Intensity (Avg. No. of Units per Enrollee per Month)
Adult Day Health Center Services			
Center Attendance	27289	99	14.9a
Social Service	3722	95	2.0a
Physician	1239	85	.7a
Nurse Practitioner	1034	40	.6a
Nursing - Routine	17738	93	9.7a
Nursing - Episodic	4588	98	2.5a
Audiology	201	38	.1a
Dentistry	229	41	.1a
Optometry	233	44	.1a
Podiatry	626	83	.3a
Psychiatry	128	17	.1a
Contracted Medical Care	264	34	.1a
Personal Care - ADL	14762	81	8.1a
Physical Therapy	4270	76	2.3a
Occupational Therapy	1871	73	1.0a
Speech Therapy	342	13	.2a
Nutritional Counseling/Education	557	79	.3a
Recreational Therapy	16571	95	9.1a

a) unit is service day, i.e. from at least 15 minutes to several hours on a given day.

(Table 4, SERVICE UTILIZATION SUMMARY continued)

	Total No. of Service Days for Period	Proportion Receiving Services (%)	Intensity (Avg. No. of Units per Enrollee per Month)
Adult Day Health Center Services (continued)			
Meals	44995	99	24.6b
Transportation - Center	21526	81	11.8c
Transportation - Other	413	62	.2c
In-Home Services Home Health Services			
Physician	38	9	<.1a
Nurse Practitioner	20	1	<.1a
Nursing	1521	71	.8a
Physical Therapy	3	1	<.1a
Occupational Therapy	6	1	<.1a
Social Services	70	14	<.1a
Supportive Services			
Personal Care/Home Chore	94987	94	51.9d
Portable Meals	34011	71	18.6b
Attendant Care	5958	17	3.3a
Inpatient Services Hospital			
Medical/Surgical Unit	323	13	.2a
Intensive Care Unit	5	<1	<.1a
Cardiac Care Unit	9	<1	<.1a
ICF/SNF			
Nursing Home Days	1738	3	.9a
Subacute Days in Nursing Home	282	1	.2a

a) unit is service day, i.e. from at least 15 minutes to several hours on a given day.
b) unit is meal.
c) unit is round-trip.
d) unit is hour of service

Comparisons with national statistics reveal On Lok's success at controlling numbers of inpatient admissions as well as lengths of stay. During the period July through December, 1988, On Lok's hospital discharge rate was 249 discharges per 1000 per annum compared to a discharge rate of 412.7 per 1000 per annum for the general 65+ population, including both well and frail elderly, 504.2 per 1000 per annum for those 75-to-84 years old and 614.8 per 1000 per annum for the 85+ population (U.S. Senate Special Committee on Aging, 1986). In terms of hospital days per 1000 per annum, On Lok's figure of 1,797 days per 1000 per annum compares very favorably to 4,004 days per 1000 per annum for the general 65+ population. During the same period, On Lok had a rate of 91.8 nursing home admissions per 1000 per annum, compared to admission rates of 46.1 per 1000 per annum for the general 65+ population, 57.7 per 1000 per annum for those 75 to 84 years old and 219.4 per 1000 per annum for the 85+ population (National Center for Health Statistics, 1987). Since all On Lok participants were certified as eligible for nursing home care at enrollment, and approximately 40 percent were 85 and older, On Lok's nursing home use is remarkably low.

These utilization patterns show that On Lok's multidisciplinary team relied on a range of day health center and home-based medical and social services to control the use of high cost hospital and nursing home services. Table 5 (see page 18) translates this utilization information into program cost, allocation terms, showing the portion of the monthly capitation rate needed to cover the cost of eight service and administrative categories.

Table 5
ALLOCATION OF CAPITATION RATE
Average for Period July, 1988 through March, 1989

COMPONENTS	PERCENTAGE	MONTHLY CAPITATION RATE
ADULT DAY HEALTH CARE	41.0	$864.69
IN-HOME SERVICES	14.6	307.91
MEDICAL CARE	10.6	223.55
INPATIENT SERVICES	11.5	242.54
MEDICAL RECORDS	1.7	35.85
PROGRAM MANAGEMENT	4.4	92.80
GENERAL ADMINISTRATION	9.6	202.46
OPERATION OF PLANT	6.7	141.30
TOTAL	100.1	2111.10

Adult Day Health Care includes: Transportation, Social Services, Nutrition, Nursing, Restorative Therapy, Recreational Therapy, Center Supportive Services

In-Home Services includes: Home Health Care, In-Home Supportive Services, In-Home Nutrition

Medical Care includes: Primary Care, Routine Specialists (e.g., Optometry, Podiatry), Outpatient Specialists, Outpatient Drugs, X-Rays, Laboratory

Inpatient Services includes: Inpatient (Med/Surg), Inpatient (ICU/CCU), Inpatient Specialists, Ambulance, Emergency Room, Nursing Home

OUTCOME MEASURES

Although attrition through death is unavoidable in a program serving only the very frail, mortality rate provides an indication of the program's quality of care. During the Risk-Based CCODA demonstration period (between 1983 and 1986), 13% of the new enrollees died, a rate of 91.5 per 1000 per annum. National statistics for 1984 show a mortality rate for the general population of 27.9 per 1000 per annum for individuals aged 65 to 74, 63.2 for those 75 to 84, and 152.9 for those 85 and older (National Center for Health Statistics, 1987). However, since all On Lok participants were certified for nursing home care, comparison with the "extensive nursing home mortality rate" for the 65+ nursing home population is probably more appropriate. This rate has been estimated to be between 186 and 276 per 1000 per annum (McConnel and Deljavan, 1982).*

QUALITY ASSURANCE

Quality assurance mechanisms not only insure appropriateness and quality of participant care but also provide an ongoing feedback system to improve services. On Lok has incorporated a number of internal and external review systems for these purposes.

Internal Quality Assurance Mechanisms

Peer Review. Inherent in the consolidated approach to service delivery is an informal system of peer review. From the point of participant assessment to the delivery and monitoring of services, each member of the team is accountable to all others for insuring the quality of every service and the delivery of services without fragmentation or delay. The participant's medical records facilitates this peer review.

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* The "extensive nursing home mortality rate" includes nursing home residents discharged to the community or to hospitals during the year and is a better measure of nursing home mortality as patients are often transferred to hospitals just before death.

Medical Records Chart Review. On Lok maintains extensive, consolidated records on each participant from the point of referral to On Lok until the point of disenrollment. Each record provides complete current and historical information on a participant's health status/management, health assessments and health care services. This comprehensive medical record improves consistency and continuity in the implementation of a participant's treatment plan. On a quarterly basis, the medical records staff reviews each chart for accurate and timely documentation of services and completeness of progress notes; any deficiencies are noted. In addition, a member of the nursing staff reviews all charts for completeness in documentation of medical care, timely referrals to medical specialists and continuity of care.

Board-Appointed Committees. On Lok has two board-level committees related to quality assurance: Medical Advisory and Ethics. Members of these committees are nominated by their chairpersons and appointed by On Lok Senior Health Services' Board of Directors.

1. Medical Advisory Committee. Comprised of one board member from the medical-dental profession, one community physician not directly affiliated with On Lok, one On Lok medical consultant, three at-large physicians and On Lok's Medical Director. The Committee is responsible for:

    - Advising the Board on medical policies,
    - Reviewing established policies and procedures required for licensure,
    - Acting as a liaison to the local medical community,
    - Reviewing participant grievances involving services provided directly by On Lok or through its medical specialty contracts,
    - Determining and maintaining standards of quality assurance in medical care, and
    - Providing overall evaluations of On Lok's written procedures for the community clinics, day health centers and home health agency.

Two committees overseen by the Medical Advisory Committee are the Utilization Review Committee and the Infection Control Committee.

- *Utilization Review Committee:* Comprised of 20 community health professionals including social workers, physicians, nurses and rehabilitation therapists who meet in groups of five to review randomly selected participant records. The purpose of the review is to evaluate the medical necessity of the skilled services provided, examine and evaluate the quality of services provided, monitor the quality of record-keeping, evaluate the records for optimum efficiency and appropriate utilization of resources, and evaluate participant needs and relevance of individual care plans.

- *Infection Control Committee:* Comprised of On Lok's Medical Director and a number of program staff who meet quarterly to develop written standards for medical asepsis and sanitation, develop a system for reporting, evaluating and tracking infections and their source among participant and staff, and develop needed training programs.

2. Ethics Committee. This committee has 20-25 members representing On Lok administrative and program staff and the community at-large in fields of primary care, pastoral counseling, law and ethics. The Ethics Committee's main responsibilities are to review treatment decisions on behalf of participants, make non-binding recommendations, review medical decisions having ethical implications, provide guidance to the Board on recurring medical-ethical issues, assist in the development of procedures in documenting Durable Power of Attorney, Do Not Resuscitate and general participant health wishes, and provide needed staff training.

Ad Hoc Program Committees. In On Lok's continuous attempt to insure quality care, three ad hoc program committees have been developed out of needs identified by service staff -- Skin Care Committee, Study Unit on Restraints and Falls, and Standards of Care Committee. All three program committees report to the board-appointed Medical Advisory Committee.

1. Skin Care Committee. Comprised of a number of program staff (administrator, center nurse, home care nurse, nurse practitioner, occupational therapist, director of training), the Skin Care Committee identifies the major risk factors accounting for skin breakdown in On Lok's population. With this knowledge, a prevention management program has been developed and incorporated at the service level. Individual participants are ranked quarterly into risk categories, preventative measures (i.e. use of specialized equipment, circulation massage) are implemented based on identified risk category, and treatment protocols are developed in both the center and the participant's home. Ongoing committee meetings review trends in skin breakdown, note the effectiveness of established procedures, and assess additional needs in staff training and/or preventative measures.

2. Study Unit on Restraints and Falls (SURF). SURF has been established to analyze patterns in participant falls, create mechanisms for identifying participants who have the propensity to fall, and develop preventative measures. This committee meets monthly to review the program's ability to manage and minimize risks to participants' safety.

3. Standards of Care. At the present time, there are no agreed upon standards of care for a community-based long-term care service program. In an attempt to fill this void, On Lok has created the Standards of Care Committee, comprised of supervisory personnel from nine service specialties, including day health, home health, nursing, medical, dietary and rehabilitation, with the intent of developing standards for a consolidated service delivery system. Ultimately, a manual will result for internal On Lok use; this manual may also serve as a guide to PACE sites for monitoring and assurance of quality care.

External Quality Assurance Mechanisms

State Licensure and Medical Audit. On an annual basis, On Lok's three adult day health centers, three community clinics and home health agency are reviewed by the State Department of Health Services. This review is conducted over a two-week period and encompasses:

- Inspection of On Lok's physical plant,
- Observation of participant and staff activities,
- Audit of participant medical records with regard to quality and continuity of care,
- Audit of personnel files with regard to staffing requirements and qualifications, and
- Interviews with select staff.

In addition, the State conducts an annual audit of On Lok's finances which focuses on revenues versus expenditures; reimbursement eligibility for individual participants; cost information on day health, inpatient and home care; and equipment inventory information.

FINANCING

On Lok was the first and is currently the only long-term care provider to pursue a risk-based approach to financing services for an exclusively nursing home certifiable population. Three basic principles collectively distinguish On Lok's financing model from traditional Medicare and Medicaid reimbursement:

1. Capitation payments are shared by Medicare, Medicaid and individuals contributing privately on the basis of their cost responsibility in the fee-for-service system.

2. Medicare, Medicaid and private pay reimbursement for acute and long-term care services is pooled in a single source of funds.

3. On Lok's capitation rate is intended to provide payers (Medicare, Medicaid and private individuals) with cost savings relative to fee-for-service expenditures for a comparable nursing home eligible population.

On Lok uses its per capita payments to cover the total cost of acute and long-term care for its nursing home eligible population. Table 6 shows how the current per capita payments are distributed among On Lok's payers: Medicare, Medicaid and the private individual, depending upon the participant's eligibility. These per capita rates are determined annually with the intent of providing On Lok with adequate funding while assuring cost savings to all payers relative to their expenditures in the fee-for-service sector.

Table 6
ON LOK CAPITATION PAYMENTS
(FY 1988-89)

Participant Eligibility	Medicare Payment	Medicaid Payment	Private-Pay Payment
Medicare only	$790	$ 0	$1420
Medicaid only (CN*)	0	1915	0
Medicaid only (MNO**)	0	1615	300
Medicare/Medicaid (CN)	790	1420	0
Medicare/Medicaid (MNO)	790	1120	300
Private Pay	0	0	2210

* Categorically needy
** Medically needy only

Medicare

The Medicare capitation payment is determined by the Adjusted Average Per Capita Cost (AAPCC) methodology developed in accordance with the 1982 Tax Equity and Fiscal Responsibility Act (TEFRA) to reimburse risk-based HMOs. Using this methodology, standardized per capita rates of payment to TEFRA HMOs are adjusted by four demographic cost factors: age, sex, welfare status and institutional status. The AAPCC methodology pays HMOs 95 percent of fee-for-service expenditures. For the On Lok program, a variant of the AAPCC was adopted. Instead of multiple adjustment factors, a single, higher cost factor is used to reflect the frailty and utilization experience of the On Lok population.

Beginning in 1986 On Lok has used a single adjustor of 2.39 times the standardized per capita rate of payment in San Francisco County. For 1989, the standardized rate of payment is $330.57 for Parts A and B combined. This figure multiplied by 2.39 generates a monthly capitation payment of $790.06 for each On Lok participant eligible for Medicare.

Medicaid

For the Medicaid portion of On Lok's capitation rate, annual negotiations take place between On Lok and the State of California Department of Health Services (DHS) at the start of the State's fiscal year in July. On Lok submits a rate proposal to DHS, as do all other prepaid health plans in the State. The formula for this proposal incorporates On Lok's service utilization patterns, costs per unit of service, and a modest cost of living adjustment. Using the State's costs for a nursing home population as the basis for comparison DHS evaluates On Lok's proposal. Currently On Lok receives monthly capitation payments of $1420 for Medicaid recipients who are categorically eligible. According to DHS, this figure represents 60 per cent of the State's expenditures for a comparable institutionalized population.

In contrast to Medicare which pays a single capitation rate for all Medicare beneficiaries, On Lok receives three separate Medicaid capitation rates depending on participants' Medicaid eligibility. The majority of On Lok participants are categorically eligible; however, some are eligible for Medicaid on the basis of medical need only. For these participants, a monthly share of cost is determined and then paid privately to On Lok. DHS reimburses On Lok the difference between the participant's share of cost and the Medicaid capitation rate. In FY '89, the average share of cost for medically needy (MNO) participants was $300 per month. Consequently, Medicaid paid On Lok an average of $1120 for MNO participants. In addition, On Lok has a small number of participants who are ineligible for Medicare. In these cases, Medicaid paid $1915.

Private Pay

Participants who are not eligible for Medicare and/or Medicaid pay one or both portions of On Lok's capitation rate privately. For those who are eligible for Medicare only, the private-pay component of On Lok's total capitation rate in FY '89 is $1420 per month. For participants with neither Medicare nor Medicaid, the total capitation rate is paid privately. Because this cost is prohibitive for most individuals residing within On Lok's catchment area, less than one percent of On Lok's population is completely private-pay. Not surprisingly, individuals who enter the program as private-pay often quickly spend down their assets and become eligible for Medicaid benefits.

Payment Issues

While On Lok's financing mechanism works reasonably well, there are certain payment issues which have required attention, particularly in anticipation of the national replication demonstration.

First, in 1986, research results showed the AAPCC demographic cost factors (age, sex, welfare status, institutional status) to be poor predictors of cost (Thomas, et al., 1985). These results were substantiated by the results of On Lok's first comparison group study which revealed Medicare costs for a long-term care population, living in the community, were 3.51 times greater than average Medicare costs (Zawadski, Shen, Yordi and Hansen, 1984). Conceptually, the standardization offered by the AAPCC is ideal for establishing On Lok's Medicare capitation rate. However, many researchers in the field of aging question the validity of the factors used in the AAPCC to set rates for the 65+ population, namely, age, sex, welfare status and institutional status. They argue that the level of functional impairment or prior utilization would provide a better basis. Thomas' study (1985) found that the AAPCC demographic factors accounted for only 0.3 percent of the variance of Medicare cost. Findings from four Medicare community long-term care demonstration projects (New York City Home Care Project, Long-Term Care Project of North San Diego County, South Carolina Community Long-Term Care Project, and ACCESS of Monroe County) suggest the appropriate adjustor may be closer to 4.0 or 4.5 for a nursing home certifiable Medicare beneficiary living in the community. Medicare's existing rate-setting methodology must be refined in order to accurately reflect Medicare's costs for a nursing home certified population living in the community.

Second, in the area of Medicaid financing, the California Department of Health Services and On Lok have developed a mutually acceptable rate-setting methodology, one which has been refined since 1984, On Lok's first year of Medicaid capitation. In so doing, the State and On Lok have had to address a number of major issues which PACE programs and their State Medicaid agencies will also confront. First, a comparable fee-for-service population must be identified for rate-setting purposes. This group's costs must be compared to the PACE program's proposed capitation rate to assure the State cost savings. But, is the comparable fee-for-service population nursing home residents or community residents certified as needing a nursing home level of care? All PACE participants are certified as eligible for nursing home care; however, it is impossible to forecast with 100 percent accuracy whether a particular individual will actually enter a nursing home from the community. Second, determining the State's total costs for a community-based population is extremely difficult. Sources of cost information may include Medicaid claims for traditional and home and community-based waiver services, and data from Title XX and Title III programs, which often provide in-home supportive and nutrition services.

Finally, participants with private insurance coverage, e.g., Medigap policies, should theoretically receive some help from their carriers with their private share of cost. During the first year of the Risk-Based CCODA, On Lok attempted to secure the interest of the insurance industry in providing capitation payments. Discussions were held with major carriers, including Blue Cross, Aetna and the Travelers, but to no avail for numerous reasons, not the least of which was the incompatibility of On Lok's capitated reimbursement system and insurers' traditional methods of operation. More specifically, traditionally covered services such as physician visits and hospitalizations were already included in the Medicare capitation rate. The low utilization of hospital and nursing home care by Risk-Based CCODA participants also rendered the Medigap policies virtually useless. Services such as meals, day health center attendance, and assistance with bathing in the home were not the kind covered by traditional insurance policies. On Lok's requests for a fixed, all-inclusive capitation payment from insurers were met with requests for bills with specific services. With the many changes taking place in the insurance industry, particularly the development of long-term care insurance products that cover home care and other community services, involvement of private carriers needs to be pursued further.

Risk-Sharing

On Lok's decision in 1983 to assume full financial risk was made only after attempts to devise a risk-sharing arrangement with Medicare and Medicaid failed. While Medicare was willing to share risk with Medicaid and On Lok, California's Department of Health Services was unfamiliar with the concept of risk-sharing and chose not to participate. In turn, Medicare opted out of a risk-sharing arrangement. For a brief period, On Lok investigated private reinsurance options, but the insurance industry's lack of actuarial data to calculate premiums and lack of prior long-term care experience rendered On Lok's efforts unsuccessful.

Consequently, On Lok chose to establish its own risk reserve, essentially reinsuring itself by setting aside 5 percent of revenues each month. The reserve was designed to cover catastrophic costs as well as fund a six-month transition period should On Lok lose its current waivers. By 1988, the risk-reserve fund had reached $1.7 million (equal to about three months' operating costs).

THE PACE DEMONSTRATION

There is general agreement that the consolidated model of long-term care is effective in On Lok's particular setting. Replication in other communities, under different organizational auspices, and in different service and funding environments, is necessary to test the model as a viable financing and service alternative to the current long-term care system.

The On Lok program represents a significant innovation in long-term health care delivery and financing. Over the past few years, On Lok has been encouraged to replicate its approach by other providers, members of the U.S. Congress, the State of California and the Health Care Financing Adminstration. Despite increasing hope that the long-term care solution On Lok has developed is generally applicable, many questions have been raised regarding its generalizability: Is On Lok's success related to the ethnicity of its predominantly Chinese client population? Are other providers willing to assume financial risk for a frail elderly population? Can a capitation rate be developed that adequately funds the program and, at the same time, is cost competitive with the fee-for-service system? Are states willing to foster the development of risk-based programs by developing systems for their administration and sharing financial risk during the initial three years of such a program's development? Are participants willing to enroll in a "lock-in" program which restricts their access to providers outside the risk-based program? Can the program provide high quality of care that impacts positively on the health and functional status of its participants? Can the program maintain financial viability under capitated reimbursement?

Through research and development funding from the John A. Hartford Foundation, the Robert Wood Johnson Foundation and the Henry J. Kaiser Family Foundation, On Lok began exploring the possibilities of working with other organizations to replicate the On Lok model. This early work from 1983 to 1985 led to a grant in December, 1985, from the Robert Wood Johnson Foundation to study the feasibility of extending On Lok's risk-based consolidated model of long-term care to other parts of the country. PACE—Program of All-inclusive Care for the Elderly—is the name of the replication effort.

Between January, 1986, and March, 1987, On Lok conducted a feasibility study to determine if organizations with the potential to replicate the model existed and if service and start-up funding would be available for implementing the model. The results of the study were impressive. More than 180 organizations, located throughout the country, expressed interest in demonstrating a variant of the On Lok model; through a structured evaluation process, six organizations were chosen by On Lok for study. Service funding for replication programs was committed through §9412(b) of the Omnibus Budget Reconciliation Act of 1986 as amended by §4118(g) of the Omnibus Budget Reconciliation Act of 1987. This legislation provides Medicaid and Medicare waivers, like On Lok's, for as many as ten public or nonprofit organizations. Start-up funding was attracted from the Robert Wood Johnson Foundation for up to six programs. Based on these results, On Lok embarked on the PACE project to replicate the model in April, 1987, with grant support from the Robert Wood Johnson and Hartford Foundations.

On Lok's Role in PACE Demonstration

Unlike other multi-site demonstrations such as the Channeling Project, the Social/Health Maintenance Organizations (S/HMOs), the Hospital Initiatives in Long-Term Care and the Living at Home Project, PACE builds upon a working model. This offers many advantages: a well-defined model, an observable working program, a sample operating system and procedures usable by others, a body of implementation experience and, most important, the availability of expertise to guide replication programs. To make the best use of these resources, On Lok has assumed a leadership role in the overall coordination of the project by providing technical support to programs as well as to project funders. During the feasibility study, On Lok identified replication candidate programs and conducted assessments of their potential to replicate the model. In addition, On Lok prepared the overall development strategy for implementation.

To assist organizations in implementing the models, On Lok provides both central management for PACE and technical assistance. Central management includes overall project planning and coordination of the PACE cross-site activities, acting as a technical advisor to funders, developing and maintaining a centralized data base, and conducting research to address program development and policy issues important to the implementation of the model. As a technical advisor to funders, On Lok endorses proposals to the Robert Wood Johnson Foundation and other foundations and waiver applications to HCFA, and monitors program performance.

PACE technical assistance activities include assisting programs to establish day health centers, developing effective team coordination, preparing proposals and budgets to secure start-up funding, securing Medicare and Medicaid waivers and developing systems to maintain information that is critical to the program's operation. The technical assistance provided to programs varies depending on individual program needs and the key development objectives each program must accomplish. Methods for providing technical assistance include both generic and individualized training programs and materials, ongoing consultation and visits.

During the period between April 1, 1988, and March 31, 1989, On Lok hosted 20 training-related visits from the eight programs participating in the national replication venture (16 from those receiving or expecting to receive Robert Wood Johnson Foundation funding and four from two other programs). These visits lasted from one-half day to five days and focused on skill development in adult day health care (6 visits), fiscal/information management (3 visits), primary medical care (2 visits), nursing (1 visit) and general orientation to the program (8 visits). On Lok's PACE staff made 26 trips to PACE sites to provide technical assistance with service development, financing, waiver applications and information system issues (20 to Robert Wood Johnson Foundation programs, 6 to the others). Each program receiving or expecting to receive support from the Robert Wood Johnson Foundation was visited by On Lok's specialists at least three times during the year

In the PACE effort, On Lok neither seeks to "franchise" its model nor take a laissez faire approach in working with replication sites. The new programs need to fit into their respective organizations and communities, yet the integrity of the model and its principles must be maintained in each setting.

Required Features

The critical components of the model which each replication site is required to incorporate in its PACE program are:

- **Target Population.** PACE programs must serve a population that is 55 years of age or older, resides in a geographically defined service area and meets the State's definition for nursing home certifiability.

- **Enrollment.** Participants enrolled in the program must accept the PACE program as their sole service provider. Once a participant is enrolled, he or she may remain in the program, regardless of changes in health status, for as long as he or she chooses.

- **Waiver Start-Up Census.** Programs must enroll sufficient census to produce revenues that support fixed costs and projected variable costs. While this census figure will vary from program to program, a minimum census of 120 must be enrolled to implement the waiver program.

- **Service Coverage.** PACE programs must provide the comprehensive range of health and social services needed by their participants, which include, but are not limited to, all Medicaid and Medicare services as described on page 9. Because the successful control of high cost services in the On Lok program has been achieved through extensive use of day health care services, the gatekeeping role of the primary care physician and tight control of contracted services, additional requirements are:

  Adult Day Health Care Services. Each program must operate an adult day health care center and provide the following services in the center: nursing, physical and occupational therapies, meals, nutrition counseling, social work, recreational therapy and personal care. To the maximum extent feasible, PACE participants must receive services in the adult day health center.

Medical Services. The physician(s), accountable to the PACE program through employment or contract, must provide primary medical care to all PACE participants. The PACE physician(s), in conjunction with the multidisciplinary team, is "gatekeeper" to the use of medical specialists and inpatient care. PACE programs must be able to meet participants' medical needs on a 24-hour basis.

Contracted Services. PACE programs can provide the following services on a contractual basis: transportation, home health services, in-home supportive services, ancillary medical services (x-ray, lab, etc.), drug, medical specialist services, nursing home services and hospital services. The program is to maintain an active contract with these providers at all times. These contracts must specify that contracted services are to be provided in accordance with the treatment plan specified by the multidisciplinary team.

- **Multidisciplinary Approach.** PACE programs must take a multidisciplinary approach to service coordination and allocation utilizing both professional and paraprofessional staff. The multidisciplinary team must include: physician, nurse, social worker, physical therapist, occupational therapist, dietician and paraprofessional representatives, i.e., drivers and health workers. Members of the multidisciplinary team must be employed by or under contract to the PACE program to insure team members' accountability. Participants must be assessed periodically, at least quarterly, by the entire team and be monitored on a routine basis.

- **Quality Assurance.** PACE programs must meet all external licensing and quality assurance standards. In addition, a mechanism must be established for external periodic audits. Internal quality assurance mechanisms must include board-level Medical Advisory and Ethics Committees.

- **Capitated Financing.** For each PACE program, a single capitation rate is developed for all of its participants. The capitation rate is fixed, regardless of changes in health status of the participants. The capitation is paid by Medicare, Medicaid and individuals depending on their eligibility. For Medicare, this payment is now set at 2.39 times the Average County Cost based on the AAPCC rate-setting methodology. For Medicaid, this payment will be negotiated between the program and State Medicaid agency based on the State's cost experience for a similar population. Participants not Medicaid eligible will pay a share-of-cost equivalent to the rate paid by Medicaid. The Medicare ACC and Medicaid rate will be adjusted on an annual basis.

- **Risk Sharing.** Unlike On Lok which assumed full risk when waiver authority was granted in 1983, PACE programs will share risk with both the Federal and State governments. Programs' financial risk will be increased gradually over a three-year period based on program performance and the risk-sharing arrangement agreed upon by the program, Federal and State governments.

- **Data Collection.** PACE programs must collect the minimum data set developed for monitoring and evaluating the PACE demonstration. Program data must be made available to HCFA, the State Medicaid agency, and On Lok on a periodic basis.

PACE Replication Sites' Role in Demonstration

Each PACE site has the formidable task of developing and/or refining service and administrative systems over a four- to five-year period, beginning with an assessment of their existing capacity vis-a-vis the model. Each site is required to develop a work plan consistent with the criteria that have been defined and/or refined by On Lok. The PACE development strategy allows each replication program to proceed at its own rate, through three phases described below.

- **Day Health Development.** A period of up to 12 months during which the program develops its day health center (based on the State's day health definition), identifies key staff for the service team and identifies a potential population for the risk-based program. A strategy for funding development costs is developed and a multi-year funding proposal is submitted to the Robert Wood Johnson Foundation or another foundation. To facilitate submittal of a waiver application during the Service Expansion period, a commitment from the State Medicaid Agency to pursue waiver authority on behalf of the program is secured.

- **Service Expansion.** A period of up to 18 months during which the program builds its service system, expands the range of services offered and prepares to initiate the Risk Management. Having secured multi-year funding to implement the risk-based program, the program now expands from a day health to a comprehensive service program, focusing particularly on the development of the primary care and home care components. The major benchmarks, here, are the primary care physician's assumption of primary care responsibilities for a portion of the caseload, and the inclusion on the multidisciplinary team of primary care and in-home service providers and the identification of the team facilitator for the risk-based program. In terms of financing, the program develops its Medicare §222 waiver application and works with its State Medicaid agency to develop an estimated capitation rate and the Medicaid §1115 waiver application. As the program gains service delivery experience, cost and client information helpful in predicting the financial viability of the model is collected.

- **Risk Management.** The three-year period during which capitated reimbursement is implemented and the team assumes control over services. Once the consolidated service delivery and financing system is ready for implementation, HCFA's approval of the site's waiver applications enables the program to move from fee-for-service to capitated reimbursement. Contracts for inpatient and medical specialty services must be implemented and the staff physician will assume primary care responsibilities for all participants. At this time, at least 120 participants need to be enrolled, each required to receive all services from the system. In addition, the program must adopt Medicare protocols and sign a contract with the State Medicaid agency specifying a rate. To manage the program effectively, the site's information system must be able to meet program management needs and project reporting requirements.

The assumption of full risk is expected to take three years, with the risk-sharing agreement established between the program, the State and HCFA exposing the program to limited risk in the first year. Financial risk will expand gradually as the program's operational experience supports the viability of the program. The rate of risk expansion will depend on the program's performance and the risk-sharing arrangement agreed upon between the program, HCFA, State Medicaid Agency and On Lok. During this period, the service system will be refined and the multidisciplinary team will increase its effectiveness in managing the full array of acute and long-term care services. Foundation support during this period will assist programs to complete the transition and build a common database across PACE programs. When programs are operating at full risk and providing a high quality of care, which should occur by the end of the third year, the reimbursement authority will become permanent.

Foundations' Role in PACE Demonstration

The Robert Wood Johnson and John A. Hartford Foundations have played a critical role in supporting both the development of individual replication programs and On Lok's central management and technical assistance activities. In February, 1987, the Robert Wood Johnson Foundation trustees awarded $4.2 million to support the PACE replication effort. These funds enable grants of up to $700,000 to each of the first six programs participating in the replication effort. Each such grant is intended to support the development and refinement of service and administrative systems at the PACE replication program over a four-year period (which overlaps with the waiver project period). In addition each of these programs is expected to raise $300,000 from local foundations to match their Johnson Foundation grant. Since federal legislation authorizes waivers for up to ten organizations, multi-year funding, similar to the Johnson grant, will be sought to support the development of four other sites.

Attachment A

LEVEL OF CARE - SKILLED NURSING FACILITY, INTERMEDIATE CARE FACILITY, RESIDENTIAL CARE FACILITY (BOARD AND CARE)

The pertinent sections in CAC, Title 22, regarding level of care determinations are 51120, 51124, 51334, and 51335.

The skilled nursing facility level of care is the level of care needed by Medi-Cal beneficiaries who do not require the full range of health care services provided in a hospital as hospital acute care or hospital extended care, but who require the continuous (24-hour) availability of skilled nursing care provided by licensed, registered or vocational nurses, or the equivalent thereof (licensed psychiatric technician). Skilled nursing care is the composite of necessary observation, assessment, judgement, supervision, documentation, and teaching of the patient and includes specific tasks and procedures. A need for one or more skilled nursing procedures does not necessarily indicate a medical need for skilled nursing facility services. Rather, the need must be for a level of service which includes the continuous availability of procedures such as, but not necessarily limited to, those listed under SNF in Table I.

Intermediate care services are services provided to persons who, because of their mental or physical condition, or both, require protective and supportive care above the level of board and care, but who do not, except for brief spells of illness, require the continuous supervision of their care by a licensed, registered or vocational nurse, and do not have an illness, injury, or disability for which long-term skilled nursing home services are required. A patient in an ICF is supervised 24 hours by nonskilled personnel and generally has available skilled nursing care during the day shift on weekdays. A patient may have 3 or 4 brief spells of illness per year requiring continuous skilled nursing care for a few days only and still qualify for ICF level of care.

Residential care (board and care) is generally for those persons who could be cared for at home if someone were available to assist them. They do not require skilled nursing care but are not quite independent enough to care for themselves. They may be under the care of a physician and require regular physician visits. They may also be taking regular or PRN medications but they should be capable of administering these medications to themselves with no more than "reminders" from the RCF personnel.

In assessing level of care, one should use common sense in viewing the patient as a whole and should not be unduly influenced or overwhelmed by any particular list of diagnoses or medications. Patients in ICFs often have multiple diagnoses and are on multiple medications but are actually stable and in quite good health and require a minimum of skilled nursing and medical care. Hearing officers should see the patient if at all possible to give them a better understanding of the total patient and their functional capacity.

LEVEL OF CARE CRITERIA - Table 1

Patient Status	Skilled Nursing Facility	Intermediate Care Facility (ICF)
1. Central Nervous System	Coma; bedfast; quadriplegia; other severe paralysis	Less severe forms of motor or sensory loss; some paraplegics
2. Cardiovascular	Stabilized but requires constant monitoring	Stabilized
3. Respiratory	Stabilized but requires constant monitoring; frequent oxygen, tracheostomy	Stabilized. Occasional oxygen
4. Gastrointestinal	Gastrostomy or other tube feeding; inability to feed self; colostomy care for initial or debilitated patients; fecal incontinence if cannot be trained	Little or no assistance feeding self. Patients with colostomy or fecal incontinence who have been trained to care for self
5. Genitourinary	Indwelling catheter in conjunction with other conditions; total incontinence	Occasional incontinence
6. Musculoskeletal	Nonambulatory	Ambulatory with or without assistive device including a wheelchair; may need assistance in transferring to wheelchair
7. skin	Dressing of postsurgical wounds; decubiti; leg ulcers. Depends on severity of lesions and frequency of dressings	Generally intact or minor lesions requiring infrequent attention
8 Mental Status	Severely incapacitated; not stable; very unpredictable; frequent adjustment of medications or injections	Mild confusion or depression; may need help in finding room; no threat to self or others; may be on stable medication regimen
9. Post Surgical	Convalescence from recent surgery, fractures, trauma	Stable, chronic

LEVEL OF CARE CRITERIA - Table 1 (continued)

	Skilled Nursing Facility	Intermediate Care Facility (ICF)
10. Other	Totally dependent; must be bathed, dressed, fed; blind or deaf unless quite independent	Minor assistance in activities of daily living (ADL); may need encouragement in restorative measures for increasing and strengthening function; may have some degree of hearing or vision loss
Institutional Services		
1. Skilled Nursing		
a. supervision and observation	Frequent intervals throughout each 24 hours; blood pressure, pulse respiration; input and output	Intermittent basis only; has 24 hour supervision by nonskilled personnel who may assist to bathroom, feeding, bathing, etc.
b. Therapeutic Procedures	Wounds, decubiti, ulcers; tube feeding, gastrostomy; tracheostomy; indwelling catheter in conjunction with other conditions; colostomy for initial and debilitated patients	Minor and infrequent care of wounds, decubiti, ulcers; indwelling catheter if otherwise stable; colostomy when trained
2. Medications	Injections more than one shift; PRN medications if nature of drug, condition being treated and frequency of need warrant SNF; use of restricted or dangerous drugs outside daytime shift; stabilizing medication*.	Mainly supportive or stabilizing. Regular doses of medications on day shift, e.g., digoxin, diuretics, high blood pressure, medications, tranquilizer, etc.
3. Rehabilitation	Bladder and bowel training. Intensive P.T., O.T., S.T. and audiology usually, but may be maintenance only. Must also require skilled nursing care and observation on 24 hour basis.	Usually P.T., O.T., S.T. and audiology on less frequent basis but may also be intensive
Physician Visits	At least monthly for first 90 days, then at least every 60 days if approved by Medi-Cal consultant	At least every 60 days, but with Medi-Cal consultant approval may be extended to every 3 months

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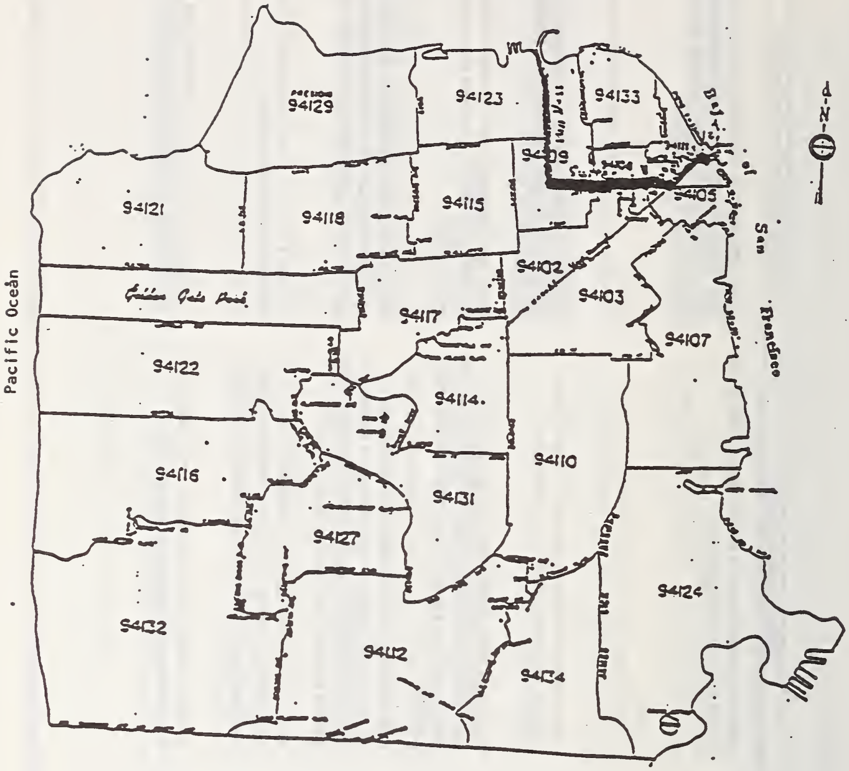
* Note: If a restricted drug such as empirin (contains codeine) is ordered PRN but required only infrequently (2-3 times/month) this does not justify SNF.

Attachment B

ZIP CODE MAPE OF
ON LOK HEALTH PLAN SERVICE AREA



NOTE: SERVICE AREA IS INSIDE THE HEAVY BLACK LINE

Mr. TOWNS [presiding]. Thank you very much for your testimony.

Let me begin with you. Given the competing Medicaid proposals before this subcommittee, what criteria should we use in determining which proposal to include in budget reconciliation?

Ms. ANSAK. Which proposals of the Medicaid—you mean among the PACE projects?

Mr. TOWNS. Yes.

Ms. ANSAK. Basically, we look at the various applicants and see if they are ready to start to go into this managed care. On Lok assesses, first of all, the capability of the organization, the population that is available for a demonstration project, the ability of the organization to initiate the program.

I don't think I could say up front which programs should be included. It depends where they are located, what the population is that can be served, and whether it is a viable program. We are very interested in only selecting those projects that have a chance to succeed at this point.

Mr. TOWNS. Given the cost controls which you have been able to establish in your program, what impact have these savings had on preserving the incomes of the participants in the program?

Ms. ANSAK. That is another difficult question, because most of the people are essentially—I mean, 95 percent of our participants are Medicaid eligible. So, those people, there is really basically no change.

For the 5 percent who are not Medicaid eligible, instead of paying an average of $3,000 or $4,000 in a nursing home, they pay a flat sum of $1,500 to On Lok, and that covers all the services, there is no additional cost. So it is a considerable saving to those people getting into the program on a private basis.

Mr. TOWNS. I know that New York State is interested in developing a similar type program. Do you believe programs such as yours can provide quality long-term care for seniors? If so, how do we answer the charges that managed care limits the kind of health services which would be available to seniors if they accessed care outside the managed care system?

Ms. ANSAK. In other words, how do we assure quality of care in a managed system?

Mr. TOWNS. Yes.

Ms. ANSAK. You know, the On Lok participants are all 55 and over. The majority is—the average age is 83. They are all already certified for nursing home care. They have an average of five diagnoses, medical diagnoses, so they are essentially a sick population.

If we do not provide adequate care and if we do not watch out very carefully, we are at risk for enormous hospitals. In other words, for us, prevention is our biggest cost saving in a way, is if we take good care and follow these people and do not let them get into an acute care situation, then we save the money.

So, I think it is in the interest—it is interesting with this elderly population—in a traditional HMO, with younger people, you can probably ignore—you can afford to ignore somebody who has some illnesses or complaint. It might not be catastrophic. If we do that, it is immediately catastrophic and the person goes into ICU and instead of paying average cost per day in a day health center, we might pay $1,000 or $1,500 a day for the hospitalization.

Mr. Towns. Thank you.

Ms. Galbraith, let me begin by saying, first of all, it is good to have you here today. I am aware of your excellent work in helping pregnant women and women with children to overcome their alcohol and drug addiction problems, and to meet their unique needs as women who are substance abusers, and I would like to commend you on your outstanding work.

You may be aware that yesterday, this committee passed out a bill to extend the program of demonstration grants for reducing the incidence of pregnant and postpartem women who abuse drugs or alcohol.

I think this is an excellent first step in opening up comprehensive treatment slots to pregnant women, and women with children.

How well are the existing grant projects faring, and what progress do you think could be achieved with the kind of expansion passed out of this committee yesterday? I would like to get your views on that.

Ms. Galbraith. I have a couple of comments. I certainly support the legislation passed out of this committee yesterday. I think it is an excellent step in establishing a system of care for women.

In answer to your second question regarding how are we doing so far, we have done miserably with the women setaside of the block grant. The States have not really complied with that Federal mandate that has been in place since 1984 to establish services for women.

I think that the OSAP pregnancy demonstration projects which are funding a little over 100 modest programs in communities, are doing fairly well. I think what they are finding is that they are setting up mechanisms for various providers, maternal and child health, child welfare and alcohol and drug services, to coordinate services.

The other thing they are finding is the biggest gap in care is residential services for women.

I think we have taken some very important steps. I think the legislation passed out of committee—although whether that will be passed out of conference by the House and Senate is another big question. I do not think that that precludes establishing a mechanism whereby Medicaid acknowledges alcoholism and drug addictions as treatable illnesses that should be covered by Medicaid, and that acknowledges for poor women in this situation comprehensive residential services are the way to go.

Mr. Towns. All right. Thank you very much. We will continue to push and to fight for this kind of legislation. We are happy that you come to share your views with us.

Let me thank both of you for your time, and your entire statements will be included in the record.

The next panel will focus on managed care issues. The first issue has to do with quality of care and follows up on a hearing this subcommittee held in Chicago in February 1988 at the request of Congresswoman Cardiss Collins. She was responding to a series of investigative articles in the Chicago Sun-Times, alleging poor quality care and underserving of Medicaid beneficiaries, including high-risk newborns by two prepaid plans.

Mrs. Collins took the initiative and followed up by requesting that the GAO look into the quality issues indepth.

Janet Shikles is Director of Health Financing and Policy Issues for the General Accounting Office. She is accompanied by Jim Linz, the Assistant Director for Health Financing. She will summarize the results of GAO's oversight report.

A second managed care issue has to do with financial integrity. In May of last year, Representative Walgren and I asked the Attorney General to look into what HealthPASS paid to deliver services to nearly 90,000 beneficiaries in west and south Philadelphia.

When the parent corporation of HealthPASS Contractor filed for bankruptcy protection, it owed participating hospitals and providers an estimated $28.4 million for services rendered to HealthPASS enrollees.

The matter is still in bankruptcy proceedings and providers have received only about one-third of the amounts owed. In the meantime, the State entered into a 5-year, $633 million contract with another firm to continue to operate the HealthPASS program.

Tom Roslewicz, the Deputy Inspector General for Audits is accompanied by Art Rafalko, the Regional Inspector General for Audits, who will give a status report on their investigation, and on contracting irregularities.

Another managed care issue relates to the capacity of those prepaid plans that enroll only Medicaid beneficiaries to deliver high-quality care. Michele Melden is a staff attorney with the National Health Law Program, Legal Services Support Center. She is here at the request of the subcommittee to share the experience of her clients.

Group Health Association of America is the oldest and largest trade association of HMO members, and serve about three-fourths of the 35 million people enrolled nationwide in HMO's. GHA is represented by Ms. Barbara Hill, president and executive director of Johns Hopkins Health Program. She is accompanied by David Siegel.

Without objection, your written statements will be included in the record. Will you please hold your initial presentation to 5 minutes or less, so we will have time to raise questions. You can begin.

STATEMENTS OF JANET L. SHIKLES, DIRECTOR, HEALTH FINANCING AND POLICY ISSUES, HUMAN RESOURCES DIVISION, GENERAL ACCOUNTING OFFICE; THOMAS D. ROSLEWICZ, DEPUTY INSPECTOR GENERAL FOR AUDIT SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES; MICHELE MELDEN, STAFF ATTORNEY, NATIONAL HEALTH LAW PROGRAM; AND BARBARA HILL, PRESIDENT, JOHNS HOPKINS HEALTH PROGRAM, ON BEHALF OF GROUP HEALTH ASSOCIATION OF AMERICA, ACCOMPANIED BY DAVID SIEGEL, MEDICAL DIRECTOR, HEALTH ALLIANCE PLAN OF MICHIGAN

Ms. Shikles. Mr. Chairman and members of the subcommittee, I am pleased to be here to discuss our recent report on oversight of Chicago area HMO's serving Medicaid recipients. Our review was requested by Representative Cardiss Collins after the Chicago Sun-

Times reported that these HMO's were providing poor quality care. The two largest are Chicago HMO and Med Care.

First, we are concerned about whether needed health care services are being provided to Medicaid recipients enrolled in these HMO's. One possible indication that there is a problem is the high turnover rate. Over 58,000 Medicaid recipients voluntarily left their HMO's during fiscal years 1986 through 1988 to return to fee-for-service. Although such disenrollments could indicate widespread dissatisfaction with the services being provided, the State has not conducted patient satisfaction surveys.

There is also little evidence in the medical records that preventive health services, such as physical examinations and immunizations, which HMO's are required to provide, are being given to children.

A review conducted in 1989 identified problems in the adequacy of prenatal care provided to pregnant women by Med Care and expressed particular concern about the care provided to high-risk mothers, such as those with medical problems or a history of substance abuse.

In another example, both HCFA and State reviewers identified instances where women were sterilized without a record of their having consented to the procedure. Neither the State nor HCFA adequately followed up to determine whether the problem was simply one of poor documentation in the medical records or a more serious quality of care problem.

This brings me to my second major concern: The lack of adequate documentation of the services provided to HMO enrollees. Without such data, it is not possible to tell whether needed services are being provided, but are just not being documented, or whether Medicaid recipients are not receiving needed services.

Our third concern focuses on the methods these HMO's use to "manage" care. These include financial incentives that, in our opinion, encourage underservicing and high turnover in HMO participation.

Med Care and Chicago HMO delegate to small groups of physicians, which function essentially as mini-HMO's, most of the responsibility for managing the care provided. That is, the groups are paid a fixed amount for a wide range of primary care services and are at risk for a substantial portion of the cost of hospital care and specialist services.

Because these groups frequently have few primary care physicians and enrollees over whom to spread the risks, a single catastrophic illness can put a financial strain on the group.

Over half of Chicago HMO's and Med Care's risk-based subcontractors had fewer than 1,000 total enrollees from these HMO's; six spread the risks over fewer than 100 enrollees. These physicians may have to make decisions that could cost themselves money or result in inappropriate reductions in service.

In conclusion, we found that effective quality assurance mechanisms are not in place in the Chicago area program to counterbalance the strong financial incentives given to Chicago HMO and Med Care primary care physicians to underserve Medicaid recipients.

Further, the effects of such incentives on patient care cannot be adequately assessed until the HMO's fully and accurately document the medical care services provided and an effective system is developed to analyze the utilization data gathered.

To address these concerns, our report contains a series of recommendations to the Secretary of Health and Human Services concerning strengthening oversight of Chicago area HMO's. Our report also recommends that the Congress amend the Social Security Act to establish, one, a minimum enrollment requirement for HMO's participating in the Medicaid program, and, two, risk-based contacting requirements for Medicare and Medicaid that are more consistent.

Mr. Chairman, that concludes my prepared statement. I would be glad to answer any questions.

[Testimony resumes on p. 380.]

[The prepared statement of Ms. Shikles follows:]

STATEMENT OF JANET L. SHIKLES, DIRECTOR, HEALTH FINANCING AND POLICY ISSUES, GENERAL ACCOUNTING OFFICE

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here to discuss our recent report on oversight of Chicago-area health maintenance organizations (HMOs) serving Medicaid recipients.[1] Our review was requested by Representative Cardiss Collins after the Chicago Sun-Times alleged, in a series of articles in October 1987, that these HMOs were providing poor quality care. The two largest Chicago-area HMOs--Chicago HMO and Med Care--were, among other things, alleged to be seriously delaying care for children and failing to provide high-risk infants with proper follow-up care.

Medicaid pays the Chicago-area HMOs a fixed monthly amount per enrolled recipient (capitation) to cover all Medicaid health services for a recipient. Capitation, therefore, gives these HMOs a financial incentive to control the use of services and assure that only necessary care is provided. Although capitation has significant potential for containing health care costs, it also poses the danger of diminished quality of care. This could happen should an HMO try to cut costs by inappropriately reducing services to Medicaid recipients.

Since 1974, the Illinois Department of Public Aid (IDPA) has contracted with HMOs for the provision of health services to

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[1] Medicaid: Oversight of Health Maintenance Organizations in the Chicago Area (GAO/HRD-90-81, Aug. 27, 1990).

Medicaid recipients. Initially, few Medicaid recipients enrolled in HMOs. In 1984, the state expanded the program to include contracting with nonfederally qualified HMOs. Subsequently, Medicaid enrollments grew rapidly. As of January 1989, about 88,000 Medicaid recipients were enrolled in the seven HMOs participating in the program.

Our review focused on the adequacy of federal and state oversight of the Chicago-area HMO program. My testimony today will address three areas of concern:

- -- inadequate identification of, and follow-up on, quality-of-care problems;
- -- inadequate documentation of the services provided so as to permit an evaluation of the quality of care; and
- -- financial incentives given to HMO physicians that could cause them to underserve Medicaid recipients.

INADEQUATE IDENTIFICATION AND FOLLOW-UP ON QUALITY-OF-CARE PROBLEMS

To begin, we are concerned about whether needed health care services are being provided to Medicaid recipients enrolled in

Chicago-area HMOs. One possible indication that Medicaid recipients are having trouble getting needed services is the high turnover of Medicaid recipients. Over 58,000 Medicaid recipients voluntarily left their HMOs during fiscal years 1986 through 1988 to return to fee-for-service.[2]

Although such disenrollments could indicate widespread dissatisfaction with the services being provided, the state has not conducted, or had the individual HMOs conduct, patient satisfaction surveys. Such a survey was planned but, state officials told us, was not done. They said the envelopes were stuffed and ready to be mailed when they were told to discontinue the survey. State officials told us they plan to conduct a patient satisfaction survey but did not know when it would be done.

There is also little evidence in the medical records that preventive health services--such as physical examinations and immunizations--which HMOs are required to provide--are being given to children. Similarly, a peer review organization (Crescent Counties Foundation for Medical Care) expressed concern during reviews in 1987 and 1988 about the adequacy of prenatal care provided to pregnant women by Med Care. A follow-up review by state quality assurance staff in 1989 confirmed the peer review findings and expressed particular concern about the care provided to high-risk mothers, such as those with medical problems or a history of substance abuse. In another example of potential quality-of-care problems, both HCFA and state reviewers identified instances where women were sterilized without a record of their having consented to the procedure. Neither the state nor HCFA adequately followed up to determine whether the problem was simply one of poor documentation in the medical records or a more serious quality-of-care problem.

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[2] Medicaid recipients remain with Med Care only about 5 1/2 months, an HMO official said.

In addition, auditors from Illinois's Department of Public Aid found that 57 percent of enrollees sampled at five Chicago-area HMOs had no record of having received services from their HMO. Another study by the peer review organization found that 30 percent of the enrollees had no record of services during 1987. The state has not, however, followed up to determine whether services provided were not documented or whether enrollees may have been denied needed services.

INADEQUATE DOCUMENTATION OF SERVICES PROVIDED

That brings me to our second concern and one of the major weaknesses in the Chicago-area program--the lack of adequate documentation of the services provided to HMO enrollees. Without such data--and a computer system to analyze it--it is not possible to tell whether needed services are being provided, but are just not being documented or whether Medicaid recipients are not receiving needed services. Even if the problem is limited to one of poor documentation, there are reasons for concern. Without complete documentation, the promptness and appropriateness of treatment cannot be assessed. The ability of a physician to make appropriate and prompt treatment decisions can be affected if test results and treatments previously given are not documented in the record.

It was only in fiscal year 1987 that Illinois began (1) requiring HMOs to submit detailed data on the health services provided to Medicaid enrollees and (2) assessing penalties for noncompliance. These actions have not been effective in ensuring the submission of complete and accurate data. As of January 1990, the state had accepted only 40 percent of the utilization data tapes submitted by HMOs. State officials told us that they have now received at least one acceptable data tape from each HMO for each quarter of fiscal year 1989, but they did not know how many more tapes should have been submitted. Without complete and accurate utilization data the state cannot detect possible underserving of Medicaid enrollees and underlying quality-of-care problems.

FINANCIAL INCENTIVES TO UNDERSERVE MEDICAID RECIPIENTS

Our third concern--and among the most serious threats to the quality of care provided to Medicaid recipients by Chicago HMO and Med Care--is the methods these HMOs use to "manage" care. These methods include financial incentives that, in our opinion, encourage underservicing and high turnover in HMO participation.

The financial incentives to control utilization vary by type of HMO. For example, some HMOs provide services through salaried primary care physicians who would not directly benefit financially by limiting the services they provide. Other types of HMOs, however, generally provide financial incentives to physicians to control (1) use of primary care services, (2) referrals to specialists, and (3) hospital admissions. The amount of financial risk transferred from the HMO to an individual physician or group of physicians increases as the physician or group of physicians is made responsible for a wider range of services, such as care by specialists and hospital care.

I want to make it clear that we are not suggesting that all HMOs in general provide poor quality care, as the Department of Health and Human Services asserted in commenting on a draft of our report. Nor are we suggesting that the same risks to patient care exist under all HMOs. The incentive payment methods used by

Chicago HMO and Med Care are, in our opinion, among the riskier models.

Med Care and Chicago HMO delegate to small groups of physicians, which function essentially as mini-HMOs, most of the responsibility for managing the care provided. That is, the groups are paid a fixed amount for a wide range of primary care services and are at risk for a substantial portion of the cost of hospital care and specialist services. Because these groups frequently have few primary care physicians and enrollees over whom to spread the risks, a single catastrophic illness can put a financial strain on the group.

Physicians may be forced to pay the cost of some care out of pocket if the cost exceeds the amounts they are paid to care for the patients. Thus, under these arrangements, substantial risk is transferred to the physicians, particularly those who have contracted to care for relatively small numbers of patients. Over half of Chicago HMO's and Med Care's risk-based subcontractors--essentially mini-HMOs--had fewer than 1,000 total enrollees from those HMOs; 6 spread the risks over fewer than 100 enrollees. These physicians may have to make decisions that could cost themselves money or result in inappropriate reductions in service.

We are particularly concerned about the amount of risk transferred to these small groups of physicians because they have not been required to (1) prove that they are financially solvent, (2) have a plan to deal with insolvency, or (3) enroll private pay as well as Medicaid recipients. Such requirements are intended to help ensure the quality of care provided to Medicaid recipients and must be applied to HMOs contracting on a risk basis to provide services to Medicaid recipients. Neither HHS nor Illinois, however, has mandated that HMOs apply these same requirements to the subcontracting mini-HMOs. This essentially permits the HMOs to circumvent federal regulations by setting up a network of mini-HMOs.

As an example, Med Care's and Chicago HMO's overall enrollments were less than the 75 percent Medicare beneficiaries and Medicaid recipients required by law. However, of the 78 subcontractors with Medicaid enrollees in Chicago HMO, 7 had over 90 percent Medicaid enrollees. Similarly, 9 of Med Care's 25 subcontractors had over 90 percent Medicaid enrollees.

We believe that financial incentive arrangements that expose the physician to substantial financial risk for services provided by other physicians or institutions or closely link financial rewards with individual treatment decisions (1) pose the greatest threat to quality and (2) necessitate the highest level of quality assurance control. These incentives, when coupled with a high turnover rate, raise concerns that physicians may increase profits by delaying care. The high turnover rate insulates the physician from adverse effects of delaying or denying care.

In conclusion, our report shows that effective quality assurance mechanisms are not in place in the Chicago-area program to counterbalance the strong financial incentives given to Chicago HMO and Med Care primary care physicians to underserve Medicaid recipients. Further, the effects of such incentives on patient care cannot be adequately assessed until the HMOs fully and accurately document the medical care services provided and an effective system is developed to analyze the utilization data gathered.

To address these concerns, our report contains a series of recommendations to the Secretary of Health and Human Services concerning strengthening oversight of Chicago-area HMOs. Both HHS and Illinois generally disagreed with our report, particularly with respect to (1) the appropriateness of the financial incentive arrangements used by Med Care and Chicago HMO and (2) the need to apply appropriate risk-based contracting requirements to subcontracting mini-HMOs. Neither HHS nor the state cited specific actions they planned to take to correct the problems. The lack of specific plans to improve quality assurance efforts heightens our concerns about the quality-of-care provided to Medicaid recipients by Chicago-area HMOs and highlights the need for congressional action to strengthen controls over the types of financial incentive arrangements used by HMOs.

Accordingly, our report recommends that the Congress amend the Social Security Act to establish (1) a minimum enrollment requirement for HMOs participating in the Medicaid program and (2) risk-based contacting requirements for Medicare and Medicaid that are more consistent. Currently, Medicare has a minimum enrollment requirement for participating HMOs while Medicaid does not. Medicaid requires appropriate contracting requirements to be applied in subcontracts while Medicare does not. We believe both requirements have merit and should apply to both programs.

Mr. Chairman, that concludes my prepared statement. I would be glad to answer any questions that you or other Members of the Subcommittee may have.

Mr. Towns. Thank you very much.

Mr. Roslewicz.

STATEMENT OF THOMAS D. ROSLEWICZ

Mr. Roslewicz. Good morning, Mr. Chairman, and members of the subcommittee. My name is Thomas D. Roslewicz. I am the Deputy Inspector General for Audit Services of the Office of Inspector General, Department of Health and Human Services. With me today is Art Rafalko, our Regional Inspector General for Audit Services for Region III in Philadelphia.

On behalf of the Department's Inspector General, Richard P. Kusserow, I am pleased to appear before you today to discuss our work concerning the HealthPASS program in Philadelphia.

Mr. Chairman, as requested, I am submitting my written statement for the record. At this time, I will briefly summarize our work performed on HealthPASS.

Much of this work came about as a direct result of Chairman Waxman's and Congressman Doug Walgren's request of May 17, 1989, that the Office of Inspector General look into the possibility that the approximately 87,000 Medicaid recipients enrolled in HealthPASS were being denied medical services or were being charged for medical services due to the initial HealthPASS contractor not paying HealthPASS providers. At the time we received your request, Mr. Chairman, the Pennsylvania Department of Public Welfare was in the process of rebidding the HealthPASS contract.

On June 21, 1989, the Inspector General reported to you and Congressman Walgren that the Health Care Financing Administration and the Pennsylvania Department of Public Welfare were closely monitoring HealthPASS to ensure that enrollees continued to have access to free medical care. We also informed you that our office would continue to monitor the HealthPASS situation.

As part of this monitoring process, we reviewed the Department of Public Welfare's award of a new HealthPASS contract to Healthcare Management Alternatives, Inc., Philadelphia, PA. This contract was effective on July 1, 1989, and was to run for a period of 4 years and 7 months at an estimated cost of $633 million.

We concluded that the Pennsylvania Department of Public Welfare had not acted prudently or wisely in the award of this contract, which was one of the largest awards made by that Department. We found that the award process was marred by a lack of documentation and a failure to comply with contract award policies established by Pennsylvania's Office of Budget.

We were concerned that the actions taken by the Department of Public Welfare gave the appearance that the basic tenet of public procurement, fair and open competition, may not have been achieved. Reasonable people could have concluded that there was the appearance of favoritism in the awarding of the HealthPASS contract.

We issued two management advisory reports on the contract award to the Health Care Financing Administration's Regional Administrator in Philadelphia. Mr. Chairman, with your permission, we would like to submit these reports, dated July 21, 1989 and October 6, 1989, for the record.

We recommended in both reports that the Regional Administrator not approve the contract with Healthcare Management Alternatives, Inc. We also referred our finding to the Federal Bureau of Investigation.

The Regional Administrator agreed with our management advisory reports and, on November 6, 1989, notified the Department of Public Welfare that the contract would not be approved. This set off a chain of events that continues to this day.

On March 5, 1990, the Regional Administrator reported to us the actions taken on our recommendations. He reported that the Health Care Financing Administration and the Department of Public Welfare agreed to resolve the issues through the execution of a memorandum of understanding which would require the Department of Public Welfare to, one, amend the term of the contract to an 18-month term ending December 31, 1990, and, two, rebid the contract effective January 1, 1991.

Mr. Chairman, the memorandum of understanding was executed on May 10, 1990, and included both requirements.

The Department of Public Welfare rebid the HealthPASS contract and, in June 1990, again selected Healthcare Management Alternatives, Inc. We understand that the Health Care Financing Administration staff in Philadelphia observed the selection process and was satisfied that Pennsylvania's procurement policies were followed. We did not monitor this process.

Mr. Chairman, this is the extent of our involvement in the HealthPASS program. This concludes my testimony. I thank you, sir, and all the members of the subcommittee for your time and attention. I will be available to answer any questions that you may have.

[Testimony resumes on p. 428.]

[The prepared statement and attachments of Mr. Roslewicz follow:]

STATEMENT BY
THOMAS D. ROSLEWICZ
DEPUTY INSPECTOR GENERAL
FOR AUDIT SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Good morning Mr. Chairman and members of the Subcommittee. My name is Thomas D. Roslewicz. I am the Deputy Inspector General for Audit Services of the Office of Inspector General, Department of Health and Human Services. I am accompanied by Art Rafalko, the Regional Inspector General for Audit Services in Region III, Philadelphia, Pennsylvania. On behalf of the Department's Inspector General, Richard P. Kusserow, I am pleased to appear before you today to discuss our work relative to the HealthPASS program in Philadelphia, Pennsylvania.

BACKGROUND

HealthPASS is a primary care case management program under which the contractor receives a capitation fee for each Medicaid recipient enrolled in the program. The program, which became operational on March 1, 1986 in selected Philadelphia neighborhoods, was authorized under a waiver granted by the Secretary of the Department of Health and Human Services on December 5, 1985.

As you know, Mr. Chairman, much of our work concerning HealthPASS came about as a direct result of your and Congressman Walgren's request of May 17, 1989, that the Office of Inspector General review the possibility that approximately 87,000 Medicaid recipients enrolled in HealthPASS were being denied medical services or were being charged for medical services due to the initial HealthPASS contractor not paying medical providers.

The initial contractor stopped paying medical providers in a timely manner after being purchased by an organization that became involved in bankruptcy proceedings. You wanted to know, Mr. Chairman, what the Health Care Financing Administration and Pennsylvania were doing to prevent a recurrence of the provider payment problems after the expiration of the HealthPASS contract on June 30, 1989.

On June 21, 1989, we reported to you and Congressman Walgren that the Health Care Financing Administration and the Pennsylvania Department of Public Welfare, hereafter referred to as the State agency, were closely monitoring HealthPASS operations to ensure that Medicaid recipients enrolled in HealthPASS continued to receive medical services free of charge. Providers were being paid through an escrow account controlled by the State agency and their Medicaid agreements with the State agency prevented them from charging Medicaid recipients.

We also reported to you that the State agency: (1) intended to incorporate into the new contract, which was to become effective on July 1, 1989, provisions requiring its and the Health Care Financing Administration's approval of any sale of the contractor to new owners; and (2) developed a contingency plan in the event that the new contract was not operational by July 1, 1989. In the event that the contract was not operational, the State agency intended to transfer all HealthPASS enrollees to the Medicaid fee-for-service program. The State agency anticipated the transfer could be accomplished without serious hardship to enrollees since most HealthPASS providers also participated in the Medicaid fee-for-service program.

We informed you that we would continue to monitor the HealthPASS situation.

MANAGEMENT ADVISORY REPORTS ISSUED BY THE OFFICE OF INSPECTOR GENERAL

As part of this monitoring process, we reviewed the State agency's award of a new HealthPASS contract to Healthcare Management Alternatives, Incorporated, Philadelphia, Pennsylvania, hereafter referred to as HMA. This contract was to run for a period of 4 years and 7 months at a cost of about $633 million.

We concluded that the State agency had not acted prudently or wisely in the award of this contract, which was one of the largest awards made by the State agency. We found that the award process was marred by a lack of documentation and a failure to comply with contract award policies established by Pennsylvania's Office of Budget. We were concerned that the actions of the State agency gave the appearance that the basic tenet of public procurement -- fair and open competition -- may not have been achieved. Reasonable people could have concluded that there was the appearance of favoritism in the awarding of the contract to HMA.

We issued two management advisory reports to the Health Care Financing Administration's Regional Administrator in Philadelphia, Pennsylvania. We recommended in both reports, dated July 21, 1989 and October 6, 1989, that he not approve the HMA contract. We also referred our finding to the Federal Bureau of Investigation for review. Mr. Chairman, copies of our management advisory reports are attached to our testimony.

Our reports concluded that the State agency did not fully comply with Pennsylvania procurement policies at critical times in the award process when the contractor was selected and when the terms of the contract were negotiated.

Selection of the Contractor

Our review of the State agency's selection process showed that, as required by Pennsylvania procurement policies, the State agency formed an Evaluation Committee to evaluate proposals submitted by bidders in response to a Request For Proposal.

This Committee was composed of one consumer activist from Philadelphia, Pennsylvania and nine Commonwealth employees with a total of 118 years experience. The Evaluation Committee established quantitative weights for five major criteria against which all of the proposals would be measured. They were (1) understanding the problem; (2) contractor qualifications; (3) professional personnel; (4) soundness of approach; and (5) costs. The Committee also established 40 minor criteria under the 5 major criteria.

The Evaluation Committee met for 5 days to review and evaluate six proposals and to select the best qualified bidder. The Committee determined that one bidder did not meet the requirements contained in the Request For Proposal for reasons that appeared valid. The remaining five bidders were measured against established criteria. The highest ranked bidder had a combined score of 87.75 and the lowest ranked bidder (which was HMA) had a combined score of 73.35. The Evaluation Committee recommended that the highest ranked bidder be selected.

According to the Committee's written report to the State agency's top management, this bidder:

1. Scored the highest in each major criteria and 26 of the 40 minor criteria.

2. Had extensive experience in processing Medicaid claims and had the best capacity to meet the project's data processing and reporting needs.

3. Established a project team that had lengthy experience in the development and/or management of third-party billing systems and Health Maintenance Organizations.

4. Demonstrated an understanding of the severe time constraints and identified the need to develop contingency plans in conjunction with the State agency.

5. Had the second highest rating for fiscal solvency and was one of two bidders that offered financial protection to the State agency by proposing that 85 percent of the monthly payments to the contractor would be placed in a separately administered escrow account.

6. Outscored all other bidders in the five minor criteria comprising development and maintenance of the provider network.

7. Outscored all other bidders in five of the six minor criteria comprising quality of care.

With respect to HMA, the Evaluation Committee recognized that HMA would have the greatest acceptance in the community because of its President's longstanding involvement in the provision of health care in the area and because it was a minority business enterprise. The Committee pointed out, however, certain weaknesses in the HMA proposal. It noted that HMA:

1. Scored the lowest in 25 of the 40 minor criteria.

2. Planned to subcontract to provide consulting services during the developmental period. The Committee was concerned that all development tasks were to be performed by the subcontractor and questioned HMA's capability and ability to assume operational responsibility on July 1, 1989.

3. Ranked the lowest in terms of fiscal solvency. The two organizations involved in establishing HMA had less than $200,000 in net working capital, much less than the other bidders. The Committee concluded that unless other capital was available to HMA, there was a question whether it could carry out the project. The Committee recommended that this issue be pursued during

oral presentations.

4. May have improperly assessed Department-furnished data files. The Committee found one flaw in HMA's analysis of this data and was concerned that other flaws in data analysis may exist resulting in a cost bid that was based on inaccurate assumptions.

By memorandum dated February 28, 1989, a Deputy Secretary of the State agency furnished the Secretary with a written report containing the Evaluation Committee's results.

As part of our review of the State agency's selection process, we reviewed the documentation supporting the ranking of the bidders and also interviewed the members of the Evaluation Committee. We concluded that, to this point in the procurement process, the State agency had complied with Pennsylvania's procurement policies, and that there was adequate documentation supporting actions taken relative to the entire award process including the Evaluation Committee's recommendation for award.

After February 28, 1989 (the date that the Evaluation Committee made its recommendation to the Secretary of the State agency), the Committee was no longer involved in the HealthPASS contract award. By memorandum dated April 7, 1989 -- which we may point out is after the selection of HMA as the contractor -- a Deputy Secretary for the first time suggested that there were problems with the work of the initial Evaluation Committee. They were:

- One, the proposal judged to be the best technically was submitted by an organization that had no experience in running a prepaid capitation program.
- Two, the Evaluation Committee, in scoring the cost factor, failed to take into account all aspects of costs.

At the point that these reported deficiencies were discovered, the State agency had two primary options available. Considering the experience of the staff on the Evaluation Committee, the effort that they expended on the evaluations, and the fact that only two of the five major criteria were apparently called into question by State agency top management, one option was to reconvene the Evaluation Committee to discuss management's concerns and/or to attend the oral presentations given by the five bidders. This option was not adopted.

The second option was to abolish the Evaluation Committee and form a second Committee. This was the option the State agency selected. There were six members on this second Evaluation Committee, two of whom served on the initial Committee.

We were able to determine that the second Committee members attended the oral presentations made by the five bidders. After giving the bidders an opportunity to revise their proposals due to an error in the some of the cost data that the State agency supplied prior to the bid submissions, the second Evaluation Committee met sometime between Friday, March 31, 1989 and Monday, April 3, 1989, to review the revised cost reports and to finalize their ranking of the bidders. According to the Deputy Secretary's memorandum of April 7, 1989, the second Evaluation Committee ranked HMA second with a score of 99.0 compared to the highest ranked bidder with a score of 99.4. The bidder ranked highest by the initial Evaluation Committee was ranked fourth by this Evaluation Committee with a score of 89.7.

The second Evaluation Committee reported to the Secretary of the State agency that the consensus of the Committee was that the best possible contractor to operate HealthPASS would be either of the two top ranked bidders. On April 4, 1989, the Secretary selected HMA, the second ranked bidder, as the contractor to operate the HealthPASS contract.

Thus, as a result of the decision to dismiss the initial Evaluation Committee, and to form a new committee, HMA rose from being ranked last in a field of five bidders to being ranked a very close second, with a 35 percent increase in its accumulated score.

Because the results of the second Evaluation Committee differed so markedly from that of the initial Committee, we attempted to obtain all documentation prepared by the second Committee to support its rankings and scores. We found that in contrast to the detailed report of the initial Committee, the second Committee did not prepare a written report of its findings and/or recommendations to the Secretary.

We also noted that members of the second Committee: had not prepared evaluation checklists called for in Pennsylvania's procurement policies; had not documented their reasons for nominating two bidders for consideration; had not documented their variation from the norm of recommending only the bidder with the highest score; and had not documented their reasons for not entering pre-award negotiations with at least the top two bidders that were only 4/10ths of a point apart in total score.

The State agency did provide us with one piece of documentation, a hand printed chart, relative to the work of the second Evaluation Committee. This chart, which is attached, was apparently the only document prepared by this Committee for the Secretary's review prior to his selecting HMA for the contract estimated at a cost of $633 million.

The chart showed summary rankings for the five major criteria. It did not provide the Secretary any indication whether members of the second Evaluation Committee had considered the 40 minor criteria used by the initial Evaluation Committee; nor was there any indication as to how each Committee member ranked individual bidders. In fact, based on the coloring system and the manner in which the chart was prepared, it appears that the ranking of one bidder was an afterthought. The ranking of another bidder was missing in its entirety from the chart.

Because of the lack of documentation surrounding the work of the second Evaluation Committee, we were unable to determine how each of the initial Committee's concerns about the HMA proposal was resolved by the second Committee. We were told that a major concern of the initial Committee relating to HMA's questionable fiscal solvency, was resolved when HMA obtained a $3 million line of credit from a bank in the District of Columbia.

The HMA did obtain a $3 million letter of credit, but our review raised a question as to whether or not the State agency actually assisted HMA in doing so. We noted that in July 1989, the State agency permitted HMA to withdraw $3 million from the HealthPASS trust fund -- all funds in this trust were considered to be Commonwealth funds -- and purchase two certificates of deposit from the same out-of-State bank where it had obtained a line of credit. We also noted that the State agency allowed HMA to establish the HealthPASS trust fund at the same bank. The State agency deposited about $11.5 million a month in the trust maintained in this bank.

Health Care Financing Administration staff in Philadelphia were reportedly told by State agency officials that the purchase of the certificates of deposit from the same bank where the line of credit was obtained was "mere coincidence." A State agency official responsible for negotiating this contract provision stated that the purpose of allowing the use of trust fund monies to purchase the certificates of deposit was to "increase the level of comfort" to the bank that was dealing with HMA.

Negotiation of Contract Provisions

Our review also showed that the State agency did not follow Pennsylvania's procurement policies for negotiating contract provisions. We found no documentary evidence that a negotiation team was formally organized or that it met as a team to discuss objectives and strategy and to develop a unified negotiation position. Whatever negotiations took place between the State agency and HMA were apparently not documented in any manner.

Because of this lack of documentation, we could not determine the extent of negotiations that occurred, the State agency's negotiation position or whether the State agency had a unified negotiation position. Therefore, there was no written assurance, in our opinion, that the State agency negotiated a fair and reasonable cost for the contract with HMA.

To the contrary Mr. Chairman, our review of certain contract provisions leads us to believe that the negotiations might have resulted in a windfall of about $29.5 million to HMA over the life of the HealthPASS contract. This included:

- $6.9 million in monthly administrative fees. This amount represents a $16.20 monthly fee for each enrollee under a total enrollment figure of 88,125. Enrollment averaged 80,342 in the first 3 full months of the contract and had not reached the stipulated figure since October 1988.

- $21.4 million in additional reimbursement for administrative costs in comparison to reimbursement received by the previous contractor.

- $1.2 million for interest earned on HealthPASS trust funds deposits.

UPDATE ON HEALTHPASS-RELATED DEVELOPMENTS

As I previously mentioned Mr. Chairman, we issued two management advisory reports to the Health Care Financing Administration's Regional Administrator in Philadelphia, recommending that he not approve the State agency's contract with HMA.

It is very important to note here, Mr. Chairman, that according to the State agency's contingency plan developed in the event that the contract would not be operational by July 1, 1989, disapproval of this contract should not have seriously affected Medicaid recipients' access to medical care. According to the State agency's plan, 3 days would have been needed to convert all HealthPASS enrollees to the Medicaid fee-for-service program. This conversion should not have required enrollees to search for new physicians or other medical providers because, again according to the plan, most HealthPASS providers also participated in the Medicaid fee-for-service program.

The Regional Administrator agreed with our management advisory reports and on November 6, 1989, notified the State agency that the contract with HMA would not be approved. This set off a chain of events that continues to this day.

On March 5, 1990, the Regional Administrator reported to us the actions taken on our recommendations. He reported that as a result of not approving the contract, lawsuits were filed against our Department by HMA, by HealthPASS providers and by HealthPASS recipients. The State agency proposed an additional suit against our Department unless a negotiated settlement could be obtained.

As part of a negotiated settlement, a court approved agreement was reached on December 6, 1989, in which the issue of the contract award was to be resolved through the execution of a Memorandum of Understanding which would require the State agency to:

- Amend the term of the contract from a 4 year 7 month term to an 18 month term ending December 31, 1990, and rebid the contract effective January 1, 1991.
- Make concessions concerning the amount of Federal funds that will be allowed under the amended contract.

On May 10, 1990, the Memorandum of Understanding was executed. The above requirements were included.

Mr. Chairman, the State agency rebid the HealthPASS contract and in June 1990, HMA was again selected. We understand that regional staff of the Health Care Financing Administration closely observed the selection process and was satisfied that Pennsylvania procurement policies were followed. We were not involved in monitoring this process. We also understand that two unsuccessful bidders have appealed HMA's selection to the State agency. The appeals were still in process as of September 5, 1990.

The Health Care Financing Administration is scheduled to receive the contract by September 30, 1990, and complete their review by November 30, 1990. It is our understanding that the new contract will include a capitation fee based on 88 percent of the fee for service rather than the 92 percent allowed under the current contract, and that the administrative fee for low enrollments will be eliminated. Other provisions favorable to the contractor have also reportedly been eliminated.

SUMMARY

Mr. Chairman, this is the extent of our present involvement in HealthPASS. As a result of our Department's scrutiny of the award of the HealthPASS contract, we believe that there have been a number of improvements. Our involvement has resulted in a new contract that, because of the reduction in the payment rate, the elimination of the administrative fee for low enrollment, and other cost concessions made by the State agency, should be less costly to the Federal Government. But perhaps even more important, Mr. Chairman, the Department of Health and Human Services put Pennsylvania, and hopefully other States as well, on notice that it will not tolerate even the appearance of favoritism in contract awards involving Federal funds.

Mr. Chairman, this concludes my testimony. I thank you, sir, and all the members of the Sub-Committee for your time and attention. I will be available to answer any questions that you may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES REGION III

Memorandum

Date July 21, 1989

From G. A. Rafalko
Regional Inspector General for Audit

Subject Review of the Pennsylvania Department of Public Welfare's Awarding of a Contract to Continue the HealthPASS Program in Philadelphia, Pennsylvania (A-03-89-00234)

To
Maurice Hartman
Regional Administrator
Health Care Financing Administration

The purpose of this management advisory report is to provide you the results of our management advisory review of the Pennsylvania Department of Public Welfare's (DPW) awarding of a contract to continue the HealthPASS program in Philadelphia, Pennsylvania. Under this program, medical services are provided to about 87,000 Medicaid recipients living in a selected area of Philadelphia.

Because of the previous contractor's precarious financial condition, DPW decided to recompete the contract to operate HealthPASS. We have been monitoring this process as a result of a congressional inquiry. Our primary objective was to determine if DPW and the Regional Office of the Health Care Financing Administration (HCFA) were taking steps to ensure that Medicaid recipients were not adversely affected by the change in contractors to operate the HealthPASS program. As part of this overall objective, we also monitored the actual awarding of the contract.

The DPW selected Healthcare Management Alternatives, Incorporated (HMA) to operate HealthPASS effective July 1, 1989. The HCFA must approve this contract if Federal financial participation (FFP) is to be available. Based on our review, we recommend that HCFA not approve this contract.

Failure to approve this contract should not adversely affect Medicaid recipients currently enrolled. According to DPW, 3 days would be required to convert all HealthPASS enrollees to the regular Medicaid program if such a change becomes necessary. This conversion would generally not require enrollees to search for new physicians or other medical providers because, according to DPW, HealthPASS providers also participate in the regular Medicaid program.

BACKGROUND

Section 1915 (b)(1) and (3) of the Social Security Act permits the Secretary, to the extent that he or she finds it to be cost effective and efficient and not inconsistent with the purposes of the Act, to waive such requirements of Section 1902 as may be necessary for a State to implement a primary care management system or a specialty physician services arrangement which restricts the provider from whom an individual can obtain medical care services, if such restriction does not substantially impair access to services of adequate quality.

On December 5, 1985, Pennsylvania received a waiver from the Secretary to operate a primary care case management program. The program, known as HealthPASS became operational on March 1, 1986 in neighborhoods included in five districts of the Philadelphia County Assistance Office.

At its inception and until July 1, 1989, the HealthPASS program was administered by Penn Health Corporation (PH) which received a capitation fee for each of the approximately 87,000 Medicaid recipients enrolled in the program. The PH was acquired by Maxicare Health Plans, Incorporated (Maxicare). Maxicare began experiencing financial difficulties and filed for Chapter 11 relief on March 16, 1989. We estimate that Maxicare owed HealthPASS providers about $28.4 million for services rendered to program enrollees as of March 1, 1989.

The DPW was aware of this growing problem with Maxicare and decided to recompete the contract. The DPW formed two evaluation committees to evaluate bidders on this contract. The initial evaluation committee screened the proposals and identified five bidders as being qualified. The five bidders were: HMA; Graduate Hospital (GH); PH; The Computer Company (TCC); and United American Healthcare (UAH). The final evaluation committee narrowed its choices to two bidders - HMA and GH - and HMA was selected by the Secretary of DPW.

According to Section 1903 (m)(2)(A)(iv) of the Social Security Act, the HCFA Regional Administrator must approve all capitated contracts in excess of $100,000. The Regional Administrator had not approved the contract as of July 21, 1989.

RESULTS OF REVIEW

Based on our review to date, we recommend that HCFA not approve this contract. We have serious concerns about the awarding of this contract including the selection of the contractor and a potential conflict of interest. Many of our concerns were also raised by HCFA staff in their review of the contract award process.

Selection of HMA

We have been able to determine that DPW established a two-step evaluation process to evaluate proposals submitted by prospective HealthPASS operators. Two evaluation committees were established. The initial committee, which consisted of 9 State employees and one consumer activist, met in February 1989 and reviewed all proposals and measured them against the following five factors: (1) understanding the problem; (2) contractor qualifications; (3) professional personnel; (4) soundness of approach and (5) cost. The initial committee determined that five bidders were qualified to operate HealthPASS. The five bidders were ranked as follows.

RESULTS OF INITIAL EVALUATION COMMITTEE

Factor	HMA	GH	PH	TCC	UAH
1	4.83	4.74	5.16	6.30	3.72
2	5.4	7.55	7.05	8.23	7.35
3	5.94	7.28	8.51	8.82	7.76
4	13.38	16.85	18.15	19.70	14.46
5	43.80	44.80	43.05	44.70	50.00
Total	73.35	81.22	82.30[1]	87.75	83.29

The final evaluation committee, consisting of six State employees, two of which were also on the initial committee, met in March 1989 to review the proposals of the five highest ranked bidders and to hear oral presentations from each bidder. The final evaluation committee, according to the documentation that we have reviewed, raised two concerns. One, the proposal judged by the initial evaluation committee to be the best technically (TCC's) was submitted by an organization that had no experience in running a prepaid capitation program. Two, the initial evaluation committee, in scoring the cost factor, failed to take into account all aspects of costs.

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[1] The total score actually adds up to 81.92. This may have been a typing error in the DPW document which we reviewed.

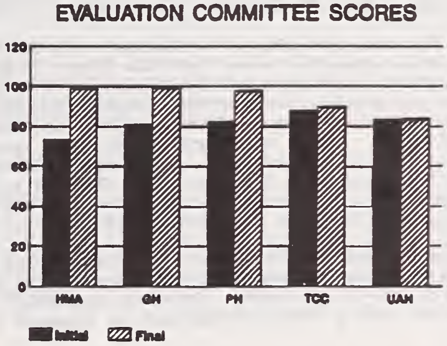
As a result of these concerns, the bidders were requested to update their bids. The final evaluation committee reviewed the updated bids and ranked the bidders according to their accumulated score.

RESULTS OF FINAL EVALUATION COMMITTEE

Factor	HMA	GH	PH	TCC	UAH
1	7.0	7.0	7.0	7.0	5.0
2	10.0	10.0	10.0	5.0	5.0
3	10.0	10.0	10.0	8.0	8.0
4	22.0	23.0	23.0	20.0	18.0
5	50.0	49.4	47.8	49.7	47.9
Total	99.0	99.4	97.8	89.7	83.9

On April 3, 1989, the final evaluation committee made its report to the Secretary, DPW. The consensus of the Committee was that the best possible contractor to operate HealthPASS would be either GH or HMA. Although GH had a slightly higher total score, HMA had the lowest bid, would require no risk-sharing by DPW and is a minority-owned business. On April 4, 1989, the Secretary selected HMA for the contract.

Our analysis of the conclusions reached by the two evaluation committees show, as illustrated below, significant differences.



EVALUATION COMMITTEE SCORES

As can be seen from the above chart, HMA benefitted the most from the review of the final evaluation committee. The HMA rose from being ranked last to being ranked second, a 35 percent increase in the accumulated score. This increase compares to 22.4 percent for GH, 18.8 percent for PH, 2.2 percent for TCC (which was ranked the best by the initial evaluation committee) and less than a 1 percent increase for UAH. We are concerned as to the basis for such changes especially since the same scoring criteria was used by the two evaluation committees.

For example, the initial evaluation committee gave HMA the lowest score for the contractor qualification factor. Yet, HMA received the highest score from the final committee, a score 85 percent higher than what was originally given. The HCFA staff, in reviewing the contract submitted by the State agency also raised concerns about HMA's ability to perform successfully. According to HCFA, HMA does not have experience operating a program the size of HealthPASS. Apparently, experience was initially viewed as an important qualification because it was this concern about TCC that led the final evaluation committee to seek revised bids. Further the HCFA staff expressed concern that HMA intends to subcontract for virtually all services. This "excessive subcontracting" could lead to separation of control from responsibility and lead to quality of service problems.

There were other concerns raised about the financial viability of HMA. The contractor was selected based on unaudited financial statements which showed relatively modest holdings. The DPW believed this was not a significant problem, however, since HMA proposed complete reinsurance of all potential losses. This was one factor which convinced the final evaluation committee to rate HMA so highly. Yet, the contract reviewed by HCFA did not even require reinsurance.

We learned that HMA is arranging with Lloyds of London to protect against losses that HMA might incur in carrying out the contract. The cost of the policy is about $4 million a year, and, according to insurance company documents, requires HMA to incur $3.5 million in losses before the reinsurance plan is activated. How a new corporation with relatively modest holdings could meet such a high deductible is questionable. The DPW points to the fact that HMA has established a $3 million line of credit at a bank in Maryland which will enable HMA to meet the deductible.

Prior to the bank's approval of HMA's line of credit for $3 million, the Commonwealth of Pennsylvania deposited $3 million in the very same bank. Based on our audit experience, it is unusual for a State Government to deposit State funds in a bank outside of the State. If the Commonwealth's deposit was a requirement for the bank to approve the line of credit for HMA, then the Commonwealth assisted HMA to achieve their reinsurance capability which was a major factor in them being awarded the contract. This, in our opinion, could constitute an unfair advantage to HMA.

Potential Conflict of Interest and Favoritism

We have identified one potential conflict of interest and we have reason to believe that HMA was treated with inappropriate preference.

The potential conflict of interest arises because the President of HMA owns several clinics in the area serviced by HealthPASS and has been providing medical care to about 3,500 HealthPASS enrollees through those clinics. Since HMA will be in a position to influence or determine referrals of Medicaid recipients to those clinics, the clinics stand to benefit if the President of HMA uses his influence to increase referrals from HMA. The HCFA pointed this out to DPW and requested a legal opinion from either the State Attorney General's Office or DPW's own attorneys that this arrangement does not violate the Commonwealth's procurement process and conflict of interest requirements. The HCFA took this approach since Federal procurement regulations (45 CFR Part 74, Appendix G) require States to follow their own procurement rules in awarding contracts. As of July 21, 1989, DPW has not provided HCFA with these assurances.

Based on the information we have obtained, it is reasonable to conclude that HMA received preferential treatment in the award of the HealthPASS contract (i.e. HMA's scores rose dramatically between the first and second reviews; lack of experience was cited as a factor in questioning another bidder's ability to perform the contract but not HMA's ability to do so; and DPW selected HMA in part because its reinsurance plan did not rely on State funding but then deposited $3 million in a bank that may have been intended to cover the deductible on that plan). We believe that these factors warrant additional investigation before any contract approval should be considered.

Conclusions and Recommendations

Based on our review, we have several concerns about the awarding of this contract to HMA. The regional HCFA staff has raised most of the same concerns that we have about this contract and the ability of the contractor to perform under it. Because of our concerns, we recommend that HCFA not approve the contract award to HMA.

JV

DEPARTMENT OF HEALTH & HUMAN SERVICES REGION III

Memorandum

Date October 6, 1989

From G. A. Rafalko
Regional Inspector General for Audit

Subject Review of the Pennsylvania Department of Public Welfare's Awarding of a Contract to Continue the HealthPASS Program in Philadelphia, Pennsylvania (A-03-89-00238)

To Maurice Hartman
Regional Administrator
Health Care Financing Administration

The purpose of this management advisory report is to provide you the final results of our management advisory review of the Pennsylvania Department of Public Welfare's (DPW) awarding of a contract to continue the HealthPASS program in Philadelphia, Pennsylvania. HealthPASS is a program under which medical services are provided to about 87,000 Medicaid recipients living in selected areas of Philadelphia.

In a management advisory report dated July 21, 1989, we alerted you to our concerns with DPW's award of this contract to Healthcare Management Alternatives, Incorporated (HMA), and we recommended that you not approve the contract award. According to Section 1903 (m)(2)(A)(iv) of the Social Security Act, the Regional Administrator, Health Care Financing Administration (HCFA) must approve all capitated contracts in excess of $100,000. Without such approval, costs incurred under the contract are not eligible for Federal financial participation (FFP).

Since the issuance of our initial report, we have performed additional work at DPW and HMA. We learned that the awarding of the HealthPASS contract to HMA represents one of the largest, if not the largest, contract awards in DPW's history. The contract runs for 4 years and 7 months and is valued at about $633 million. A prudent and reasonable person would expect that, for such a large expenditure of taxpayer dollars (both Commonwealth and Federal tax dollars are involved since HCFA was to share in the contract costs), every stage of the contractor selection and negotiation process would be precisely documented to avoid the existence of or the appearance of favoritism or other improprieties in the award and/or negotiation process, and to demonstrate to taxpayers that the process resulted in fair and open competition.

In our opinion, DPW, contrary to contract award procedures established by the Commonwealth's Office of Budget, did not adequately document its actions during the critical contractor selection and negotiation stages of this contract award process. During the initial stages of the procurement process, DPW strictly adhered to the Commonwealth's procurement procedures and fully documented its actions.

In contrast, the later stages of the procurement process, when HMA was selected and negotiations were held, were conspicuously devoid of documentation supporting selection of the second ranked bidder and inclusion of several provisions in the contract that appear extremely lucrative for the contractor. For instance, there is no adequate documentation to support:

... how HMA rose from being ranked the last of five bidders to being ranked second.

... why DPW selected HMA, an organization that was incorporated just one day prior to submitting its bid proposal to DPW, rather than following the norm of selecting the highest ranked bidder, an organization which was solidly entrenched in the Philadelphia health care community.

... why DPW allowed Commonwealth funds of about $11.5 million to be deposited monthly in a District of Columbia bank (the same bank from which HMA obtained a $3 million line of credit), and then denying, as late as August 4, 1989, that this was happening.

... the reasonableness of three contract provisions which could result in a windfall of $29.5 million to HMA over the life of the contract.

In addition, there is also a lack of adequate documentation to support the reasonableness of a $1.5 million developmental contract that was awarded to HMA just two days after they were selected for the HealthPASS contract. Our review at HMA showed that they were not able to safeguard these funds. Internal controls were virtually non-existent. Payments were made without approval by HMA management, without receipts, without assurance that services were required and without assurance that services paid for were rendered. Many HMA expenditures charged to the developmental contract were unreasonable, unallowable and, in some cases, extravagant.

We also reviewed a letter from DPW to you dated September 18, 1989. Neither our review of the contents of the letter nor the results of our additional reviews at DPW and HMA have resulted in any information that would alter our previous recommendation with respect to approving the HealthPASS contract. To the contrary, we are more than ever convinced that there exists, at the very least, the appearance of favoritism in this contract award and that such appearance can erode public confidence in the government procurement process.

We, therefore, recommend that HCFA:

... should not approve the DPW contract;

... should not approve DPW's claims for FFP under the HealthPASS contract awarded to HMA, and

... should not approve DPW's claims for FFP under the developmental contract awarded to HMA.

BACKGROUND

Section 1915 (b)(1) and (3) of the Social Security Act permits the Secretary, to the extent that he or she finds it to be cost effective and efficient and not inconsistent with the purposes of the Act, to waive such requirements of Section 1902 as may be necessary for a State to implement a primary care management system or a specialty physician services arrangement which restricts the provider from whom an individual can obtain medical care services, if such restriction does not substantially impair access to services of adequate quality.

On December 5, 1985, Pennsylvania received a waiver from the Secretary to operate a primary care case management program. The program, known as HealthPASS, became operational on March 1, 1986 in neighborhoods included in five districts of the Philadelphia County Assistance Office.

At its inception and until July 1, 1989, the HealthPASS program was administered by Penn Health Corporation (PHC) which received a capitation fee for each of the approximately 87,000 Medicaid recipients enrolled in the program. The PHC was acquired by Maxicare Health Plans, Incorporated (Maxicare). Maxicare began experiencing financial difficulties and filed for Chapter 11 relief on March 16, 1989. We estimate that Maxicare owed HealthPASS providers about $28.4 million for services rendered to program enrollees as of March 1, 1989.

The DPW decided to recompete the HealthPASS contract. The HMA was selected as the contractor to operate the HealthPASS program in Philadelphia, Pennsylvania. The contract, which was effective July 1, 1989, is for 4 years and 7 months and is valued at $633 million. The DPW makes monthly capitation payments to a trust fund maintained in a District of Columbia bank named in the contract. Under the terms of the contract, the funds remain Commonwealth funds as long as they are in the trust.

On April 6, 1989, two days after selecting HMA as the contractor for HealthPASS, DPW awarded HMA a developmental contract for $1,474,340 for the period April 6 to June 30,

1989. The objective of this contract was to develop a system of primary care case management for the HealthPASS program. At the time of our review, HMA had submitted claims totaling $1,161,582. The HMA had yet to submit its final cost report for the developmental contract, thus additional claims are possible.

The Office of Inspector General was requested by two members of Congress to monitor the HealthPASS program to ensure that Medicaid recipients were not adversely affected by the change in contractors. As part of this overall objective, we also monitored DPW's award of the contract to HMA.

We issued a management advisory report to HCFA on July 21, 1989, recommending that they not approve the contract awarded by DPW to HMA to operate the HealthPASS program. We pointed out that many of our concerns were identical to HCFA's concerns. We understand that HCFA has still not approved the HMA contract.

METHODOLOGY

Our review was initially limited to monitoring the actions taken by DPW and HCFA relative to the change in HealthPASS contractors. We subsequently expanded our review to include the actual contract award process. Our objective was to determine if DPW adhered to contracting procedures established by the Commonwealth's Office of Budget to prevent either the existence of, or the appearance of, favoritism in the award process and to inspire public confidence in the procurement process. We did not perform an evaluation of the bid proposals.

We expanded our review to include the costs claimed by HMA under the developmental contract awarded by DPW. The contract was for a total of nearly $1.5 million. At the time of our review, HMA claimed almost $1.2 million of costs under the contract. Our purpose was to determine the allowability of the claimed costs.

Our review was conducted at DPW in Harrisburg, Pennsylvania and HMA in Philadelphia, Pennsylvania during the period May through September 1989.

RESULTS OF REVIEW

COMMONWEALTH CONTRACTING PROCEDURES

The Office of Budget, Commonwealth of Pennsylvania has established standard procedures, definitions and guidelines for preparing and processing contracts. These procedures are found in an Office of Budget manual (M.215.1) entitled Contracting for Services which has been approved by the Office of General Counsel and the Office of Attorney General.

The purpose of this manual is to ensure fair and open competition which is a "basic tenet of public procurement". Competition reduces the opportunity for favoritism and inspires public confidence that contracts are awarded equitably and economically.

A Request for Proposal (RFP) procurement is used to obtain services such as those provided under the HealthPASS program. The RFP requires detailed information from potential contractors concerning understanding of the problem to be solved, services to be provided, and the approach to be used in solving the problem or providing the service.

After the issuance of the RFP, the Commonwealth procedures call for a preproposal conference, receipt of proposals and, most important of all, evaluation of proposals. The purpose for evaluating proposals is to "assist the Evaluation Committee in the objective evaluation of contractor proposals and the ultimate selection of the best possible service at the lowest overall cost to the agency".

The Evaluation Committee is to be composed of individuals who possess the technical and managerial expertise in the appropriate field as well as those with experience. The duties of an Evaluation Committee are to:

... establish checklists identifying mandatory requirements and assure that qualitative evaluation criteria contained in the RFP have been reduced to weighted checklists;

... screen all proposals to determine which of them meet mandatory requirements;

... evaluate proposals that meet mandatory requirements and rank them in order of merit based on evaluation criteria contained in the RFP;

... recommend contractor selection.

The evaluation of proposals that meet the requirements of the RFP is to be conducted in several stages:

> In Stage 1, the Evaluation Committee is to make a tentative technical evaluation of the proposal. This stage of the evaluation process may include oral presentations by contractors, generally to clarify

> specific aspects of a contractor's proposal. The letter to the contractor requesting the verbal presentation should include a list of the specific items the contractor should address, the time the contractor will be allowed for the presentation and the identity of any specific person the agency wants to participate in the contractor's presentation.
>
> **In Stage 2**, the Evaluation Committee is to make a tentative evaluation of costs.
>
> **In Stage 3**, if circumstances clearly justify, the Evaluation Committee is to enter pre-award negotiations with three or four contractors whose proposals have received top combined cost and technical ratings. Negotiations shall be conducted in such a manner fair to all contractors involved in the negotiations and in the best interest of the Commonwealth. During these negotiations all committee members should be present and actively assist the negotiator. The negotiations should be tape recorded if convenient; if not, a record must be made of the substance of the agreement.
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> **In Stage 4**, the Evaluation Committee is to finalize its rankings of proposals taking into consideration changes effected during negotiations.

Upon completion of the evaluations, the Committee will rank bidders according to the total score assigned to each, in descending order. **The contractor with the highest score is normally recommended for award.** The Evaluation Committee's recommendation together with supporting workpapers should be forwarded to the issuing office. The recommendation should include the reasons for selecting the contractor and the Committee's RFP Requirements and Evaluation checklists. Examples of this checklist, which is used by individual committee members to evaluate proposals, are included as Exhibits 7 and 8 of the Office of Budget's manual.

After the evaluations have been completed and the selected contractor notified, contract negotiations occur. A negotiation team is to be designated and the team is to meet prior to negotiations with the contractor to establish objectives and strategy. Negotiations should be tape recorded or a stenographer should record all agreements reached and other pertinent portions of the negotiations.

SELECTION OF THE CONTRACTOR

The Office of Budget's contract award procedures stress objectivity and documentation throughout the award process, even to the extent of tape recording proceedings. If these procedures are adhered to, the contract award process should result in fair and open competition. If the procedures are not followed, the possibility exists that fair and open competition may not result, or as bad, may appear not to result.

During the early stages of the HealthPASS contractor selection process, DPW complied with Commonwealth procurement procedures. On November 4, 1988 DPW mailed RFPs to 54 bidders. The cover letter specified that a preproposal bidder's conference would be held on November 28, 1988 and that the final submission date for proposals would be January 31, 1989. According to the cover letter "late proposals will not be considered regardless of the reason". On November 28, 1988 the preproposal bidder's conference was held as scheduled and representatives from 24 prospective bidders attended.

First Evaluation Committee Documented Its Work

The DPW also selected an Evaluation Committee as required by the Commonwealth's procurement procedures. The Evaluation Committee consisted of one consumer activist from Philadelphia, Pennsylvania and nine Commonwealth employees. The positions they held within the Commonwealth were as follows:

Program Analyst, Office of Budget
Manager, Bureau of Financial Operations
Director, Bureau of Special Medical Assistance Programs
Director, Bureau of Income Maintenance Operations
Special Assistant to the Secretary
Director, Division of Administration and Planning
Director, Division of Case Management Programs
Program Specialist, Division of Case Management Programs
Office of the Comptroller (Ex-Officio)

These nine individuals had a total of 118 years experience with DPW at the time the Committee was established. Based on their experience and positions, these individuals appeared to have the qualifications necessary for participation in this evaluation committee.

Documentation showed that this Evaluation Committee first met on January 19, 1989 to be briefed on the contract award process and to establish criteria against which all bid proposals would be reviewed. Using the Evaluation Checklist shown in the Office of Budget's manual (Exhibit 8), the Evaluation Committee established quantitative weights for five major criteria and agreed on 40 minor criteria as shown:

	Major Criteria	Weight	Minor Criteria
1.	Understanding the Problem	.0143	6
2.	Contractor Qualifications	.0192	7
3.	Professional Personnel	.02	6
4.	Soundness of Approach	.0158	21
5.	Cost	.50	

Although the bids were initially required to be submitted by January 31, 1989, DPW published a flyer on January 18 extending the bid response date to February 10, 1989. The only documentation that we could find relative to this extension was a letter dated January 13, 1989 from Atlantic Systems Incorporated requesting the bid response date be extended to February 28, 1989. (Atlantic Systems Incorporated is part of the joint venture that resulted in the formation of HMA). The DPW responded to this letter on January 27, 1989 by notifying Atlantic Systems Incorporated of the extension of the bid response date to February 10, 1989 and explained that time constraints prevented further extension.

On February 10, 1989, the revised bid response date, six bids had been received by DPW. The six bidders were HMA; PHC; The Computer Company (TCC); United American Healthcare Corporation (UAHC); Graduate Hospital and John Hancock HealthPlan of Pennsylvania (GH/JH) and Mercy Health Plan (MHP).

The Evaluation Committee met between February 13 and February 17, 1989, to review and evaluate the six proposals and to select the best qualified bidder. The Committee determined that MHP did not meet the RFP requirements for reasons that appeared valid. The Committee had questions concerning the five remaining proposals and requested additional information from the bidders. The bidders had until February 27, 1989 to provide the requested information.

The information was received by the required date and the Evaluation Committee made the final rankings of the bidders. Each Committee member completed an evaluation checklist which showed their ranking of each bidder for the five major criteria and 40 minor criteria. As noted below, the highest ranked bidder was TCC with a combined score of 87.75 and the lowest ranked bidder was HMA with a combined score 73.35.

RESULTS OF INITIAL EVALUATION COMMITTEE

Criteria[1]	HMA	GH/JH	PHC	TCC	UAHC
1	4.83	4.74	5.16	6.30	3.72
2	5.4	7.55	7.05	8.23	7.35
3	5.94	7.28	8.51	8.82	7.76
4	13.38	16.85	18.15	19.70	14.46
5	43.80	44.80	43.05	44.70	50.00
Total	73.35	81.22	82.30[2]	87.75	83.29

The Evaluation Committee recommended that TCC, the highest ranked bidder, be selected. TCC had outscored the next highest bidder by 4.46 points or 5.3 percent. According to the Committee's written report to the Secretary, TCC:

1. Scored the highest in each major criterion and 26 of the 40 minor criteria.
2. Had extensive experience in processing Medicaid claims and had the best capacity to meet the project's data processing and reporting needs.
3. Established a project team that had lengthy experience in the development and/or management of third-party billing systems and Health Maintenance Organizations (HMOs).
4. Demonstrated an understanding of the severe time constraints and identified the need to develop contingency plans in conjunction with DPW.
5. Had the second highest rating for fiscal solvency and was one of two bidders (PHC was the other) that offered financial protection to DPW by proposing that 85 percent of DPW's monthly payments to the contractor would be placed in a separately administered escrow account.
6. Outscored all other bidders in the five minor criteria comprising development and maintenance of the provider network.

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[1] See page 8 for identification of the five major criteria.

[2] The total score actually adds up to 81.92. This may have been a typing error in the DPW document which we reviewed.

7. Outscored all other bidders in five of the six minor criteria comprising quality of care.

The Committee also expressed some concern about delays experienced in TCC's processing of fee-for-service claims for DPW, and requested some current information on the financial status of TCC's parent company. The Committee recommended that both issues be addressed at the oral presentation.

In sharp contrast to TCC's favorable evaluation, HMA fared poorly. The Committee recognized that HMA would have the greatest acceptance in the community because of HMA's President's longstanding involvement in the provision of health care in the area and because it is a minority business enterprise. The report pointed out, however, many weaknesses in the HMA proposal. It noted that HMA:

1. Scored the lowest in 25 of the 40 minor criteria.

2. Plans to subcontract with American International Healthcare (AIH) to provide consulting services during the developmental period. The Committee was concerned that all development tasks were to be performed by AIH rather than HMA and questioned HMA's capability and ability to assume operational responsibility on July 1, 1989.

3. Ranked the lowest in terms of fiscal solvency. The two organizations involved in establishing HMA have less than $200,000 in net working capital, much less than the other bidders. The Committee concluded that unless other capital was available to HMA, there was a serious question whether HMA could carry out the project. The Committee recommended that this issue be pursued during the oral presentations.

4. Analysis of DPW furnished data files was suspect. The Committee found one flaw in the analysis and was concerned that other flaws in the data analysis may exist resulting in a cost bid that was based on inaccurate assumptions.

By memorandum dated February 28, 1989, the Deputy Secretary for Medical Assistance Programs furnished the Secretary with a written report containing the Evaluation Committee's results. Attached to the report was summary information on each of the proposals, listing their strong and weak points, and a chart indicating how each individual on the Committee ranked each proposal. The Deputy Secretary stated that they would await the results of the oral presentations before proceeding with contract negotiations. The Deputy Secretary's memorandum did not refer to any flaws or weaknesses in the Evaluation Committee's work.

We reviewed the documentation supporting the above scores and also interviewed all 10 committee members. We verified that the committee members spent five full days from February 13 to 17, 1989 reviewing and evaluating the bid proposals. We also reviewed the individual evaluation checklists prepared by each of the committee members. The checklists, with the exception of a few insignificant mathematical errors, supported the above ratings.

In our interviews with the Evaluation Committee members, we learned that they were aware of the Commonwealth's procurement procedures and had thoroughly documented the results of their review. We were able to conclude that, to this point, DPW had complied with the Commonwealth's procurement policies and had adequate documentation supporting actions taken relative to the entire award process including the first Evaluation Committee's recommendation for award.

Second Evaluation Committee's Efforts Not Documented in Accordance With Commonwealth Procurement Procedures

After February 28, 1989, the date that the first Evaluation Committee made its recommendation, they were no longer involved in the HealthPASS contract award. A memorandum dated April 7, 1989 (the contractor was already selected at that time) written by the Deputy Secretary for Medical Assistance Programs suggests that there were two major problems with the work of the first Evaluation Committee. One, the proposal judged to be the best technically was submitted by an organization that had no experience in running a prepaid capitation program. Two, the first Evaluation Committee, in scoring the cost factor, failed to take into account all aspects of costs.

At that point, there were two principle options available to DPW. Considering the experience of the staff on the first Evaluation Committee, the effort that they expended on the evaluations, and the fact that only two of the five major criteria were apparently called into question by DPW top management, one option would have been to reconvene the first Evaluation Committee to discuss management's concerns and/or to attend the oral presentations given by the five bidders. This option was not adopted. We learned through interviews that most of the members on the initial Evaluation Committee were not contacted on this matter and most were not aware that DPW was concerned about their recommendation for selection.

The second option was to establish a second Evaluation Committee. This was the option selected by DPW. Because of lack of documentation, we could not determine exactly when this Committee was formed but it was sometime around March 1, 1989. There were six members on this Committee, two of whom (identified by a * below) served on the first Committee, and they held the following positions within the Commonwealth government.

Deputy Secretary for Medical Assistance Programs
*Director, Bureau of Special Medical Assistance Programs
*Program Analyst, Governor's Office of Budget
Special Assistant to the Secretary
Director of Procurement
Chief Counsel, DPW

We were able to determine that the Committee members attended the oral presentations made by the five bidders. These presentations were made on March 1 and March 6, 1989. Sometime after that DPW reportedly noted that some of the cost data supplied to interested bidders was inaccurate. By letter dated March 23, 1989, DPW notified the five bidders of the inaccuracy and gave them until March 31, 1989 to submit revised cost proposals. Two of the bidders -- HMA and TCC -- responded with revised cost proposals. Two other bidders -- UAHC and GH/JH -- responded that their original bids were accurate.

Sometime between Friday, March 31, 1989 and Monday, April 3, 1989, the second Evaluation Committee apparently met to review the revised cost reports and to finalize their ranking of the bidders. According to the Deputy Secretary's memorandum of April 7, 1989, the second Evaluation Committee ranked the bidders as follows.

RESULTS OF SECOND EVALUATION COMMITTEE

Criteria	HMA	GH/JH	PHC	TCC	UAHC
1	7.0	7.0	7.0	7.0	5.0
2	10.0	10.0	10.0	5.0	5.0
3	10.0	10.0	10.0	8.0	8.0
4	22.0	23.0	23.0	20.0	18.0
5	50.0	49.4	47.8	49.7	47.9
Total	**99.0**	**99.4**	**97.8**	**89.7**	**83.9**

The April 7, 1989 memorandum also stated that on April 3, 1989, the second Evaluation Committee made its report to the Secretary, DPW. According to this memorandum, the consensus of the Committee was that the best possible contractor to operate HealthPASS would be either GH/JH or HMA, the two highest ranked bidders. As shown above, GH/JH was ranked first and HMA was ranked second. On April 4, 1989, the Secretary selected HMA, the second ranked bidder, as the contractor to operate the HealthPASS contract.

Based on our review of detailed documentation prepared by the first Evaluation Committee and the April 7, 1989 memorandum prepared on behalf of the second Evaluation Committee after the contractor had been selected, we noted significant differences in the Committees' rankings and scores as shown below:

Committee	HMA	GH/JH	PHC	TCC	UAHC
One	73.35	81.22	82.30	87.75	83.29
Two	99.0	99.4	97.8	89.7	83.9
Difference	**+25.65**	**+18.18**	**+15.50**	**+ 1.95**	**+ .61**
Percentage	**+35%**	**+22.4%**	**+18.8%**	**+ 2.2%**	**+ 0.1%**

As can be seen from the above chart, HMA benefitted the most from the review of the second Evaluation Committee. The HMA rose from being ranked last to being ranked second, a 35 percent increase in the accumulated score. The following chart illustrates how HMA's ranking and scores changed.

Criteria	First Committee		Second Committee		Score
	Rank	Score	Rank	Score	Change
1	3	4.83	1	7.0	+44.9%
2	5	5.4	1	10.0	+85.2%
3	5	5.94	1	10.0	+68.3%
4	5	13.38	2	22.0	+64.4%
5	4	43.80	1	50.0	+14.2%
Overall	**5**	**73.35**	**2**	**99.0**	**+35.0%**

Because the results of the second Evaluation Committee differed so drastically from that of the first, we attempted to obtain all documentation prepared by the second Committee to support its rankings and scores. We found that in sharp contrast to the detailed memorandum of February 28, 1989 transmitting the first Committee's report to the Secretary, the second Committee did not prepare a written report of its findings and/or recommendations to the Secretary.

We also noted, again in sharp contrast to the documentation prepared by the first Committee, that members of the second Committee: had not prepared evaluation checklists called for in the Commonwealth's contracting procedures; had not documented their reasons for nominating two bidders for consideration; had not documented their variation from the norm of recommending only the bidder with the highest score; and had not documented their reasons for not entering pre-award negotiations with at least the top two bidders (GH/JH and HMA) that were only 4/10ths of a point apart in total score.

Regarding the latter issue, Commonwealth procurement procedures allow for pre-award negotiations when clearly justified. In our opinion, pre-award procedures were clearly justified in this case considering the amount of money involved and the fact that two bidders received similar scores. The basic differences in their ranking involved two major criteria.

... The GH/JH was ranked a full point higher in criterion 4, soundness of approach. Because the second Evaluation Committee did not adequately document their proceedings, we could not determine why they ranked GH/JH higher in this criterion. It may have been because of what the first Evaluation Committee termed GH/JH's innovative approaches for securing community representation and participation. One of these innovations called for GH/JH to donate to community projects 2 percent of their profits from operating HealthPASS, up to a maximum of $250,000. A pre-award negotiation with both bidders could have resulted in GH/JH increasing their offer or, more importantly since HMA ultimately was selected as the contractor, HMA making a similar offer.

... The HMA was ranked 6/10ths of a point higher in criterion 5, cost. Again, due to lack of adequate documentation, we cannot determine the justification for the rankings. We noted, however, that a major reason cited by DPW for selecting HMA as the contractor was HMA's proposal to purchase reinsurance to protect DPW from any risk of loss. A pre-award negotiation with GH/JH may have resulted in a similar proposal.

The DPW did provide us with one piece of documentation, a hand-printed chart, a picture of which is included as Attachment A to this report. Incredibly, this single chart is apparently the only document that was prepared by the Committee for the Secretary's review prior to him selecting the contractor. The document showed summary rankings for the five major criteria. It did not provide the Secretary any indication that Committee members even considered, let alone measured the bidders' proposals against, the 40 minor criteria used by the first Evaluation Committee; nor is there any indication as to how each Committee member ranked individual bidders. In fact, based on the coloring system and the manner in which it was written, it appears that ranking of one bidder (UAHC) was an afterthought. The ranking of another bidder (PHC) is missing in its entirety from the chart.

Issue Raised by First Committee Regarding HMA's Fiscal Solvency

Because of the lack of documentation surrounding the work of the second Evaluation Committee, we could not determine how all of the first Committee's concerns about the HMA proposal were resolved by the second Committee. We were told that a major concern of the first Committee, that is HMA's questionable fiscal solvency, was resolved when HMA obtained a $3 million line of credit from a bank in the District of Columbia.

We did not obtain any information directly from the bank but we did obtain documentation indicating that a line of credit was granted by the bank to HMA. We also noted that in July 1989 HMA made a $3 million withdrawal from the trust fund (all funds in this trust are considered to be Commonwealth funds) and purchased two Certificates of Deposit (CDs) from the same bank where it obtained a line of credit. Reportedly, DPW informed HCFA that purchasing the $3 millon in CDs from the same bank where the line of credit was obtained was "mere coincidence".

A DPW official responsible for negotiating this contract provision informed us that the purpose of allowing the use of trust fund monies to purchase the CDs was to "increase the level of comfort" to the bank that was dealing with HMA. This statement, in our opinion, contrasts sharply from DPW's statement to HCFA. Rather than just being a coincidence as originally portrayed by DPW, HMA's purchase of $3 million in CDs from the bank appears to be tied in to their maintaining a $3 million line of credit with the same bank.

In the same vein, we noted that DPW allowed HMA to establish the trust fund at the District of Columbia bank. The DPW deposits about $11.5 million a month in the trust maintained in this bank. In our opinion, maintaining the trust in this bank gives the appearance of another effort on the part of DPW to provide "additional comfort" to the bank insofar as the line of credit is concerned. As late as August 4, 1989, DPW was denying this to HCFA, insisting that the trust was maintained in a Pennsylvania bank.

We discussed this issue with representatives from the Commonwealth's Treasurer's Office. Preliminary indications are that Commonwealth funds are required to be deposited in banks approved by the Treasurer's Office and located within the Commonwealth. We were informed that the Inspector General for the Treasurer's Office will investigate this apparent breach of policy and will issue a report shortly.

If DPW is required to halt all deposits in the District of Columbia bank and, instead, deposit all Commonwealth funds in an approved bank located within the Commonwealth, it is possible that HMA's line of credit with the District of Columbia bank may be jeopardized. Obviously the increased level of comfort referred to by the DPW official will no longer exist.

Regardless of the outcome of the Treasurer's Office investigation, DPW's actions in allowing the purchase of the CDs and the establishment of the trust fund in the District of Columbia bank give the appearance that DPW helped HMA achieve a degree of fiscal solvency. If so, DPW's actions represent an unfair advantage to the contractor.

NEGOTIATIONS WITH THE SELECTED CONTRACTOR

Apparently negotiations between DPW and HMA began immediately after April 4, 1989, the day that HMA was selected as the contractor. Two days later, on April 6, 1989, DPW awarded HMA a developmental contract for about $1.5 million to prepare for the start of HealthPASS operations on July 1, 1989. Apparently negotiations continued up to July 1, 1989, when the contract to operate the HealthPASS program was signed by both parties. We say apparently because DPW failed to document contract negotiations involving $633 million of public funds.

According to Commonwealth procurement policy, a negotiating team should be designated by the awarding agency. The team, which is to include technical, contracting, fiscal and legal expertise, should be headed by a chief negotiator. Prior to negotiations, the team should meet to present objectives and strategy and to develop a unified negotiation position. Negotiations conducted by the team should be tape recorded or documented with the assistance of a stenographer.

The DPW did not follow these procedures. Similar to the situation we found with the second Evaluation Committee, the negotiation process was remarkable for its lack of documentation. We found no documentary evidence that a negotiation team was formally organized or that it met as a team to discuss objectives and strategy and to develop a unified negotiation position. Whatever negotiations took place between DPW and HMA were neither tape recorded nor recorded by a stenographer. In fact, we found no documents whatever supporting the contract provisions agreed to by both parties.

Because of this lack of documentation, we could not determine the extent of negotiations that occurred, DPW's negotiation position or whether DPW even had a unified negotiation position. Therefore, there is no assurance that DPW negotiated a fair and reasonable cost for either the developmental contract or for the HealthPASS contract. To the contrary, our review of certain provisions leads us to believe that DPW negotiations could result in a windfall of about $29.5 million to HMA over the life of the HealthPASS contract. In our opinion, more reasonable and economical terms may have been achieved through a more structured and effective negotiation process. For example:

Provision for Payments of Administrative Fee

Under the terms of the contract, DPW pays HMA an "administrative fee" of $16.20 per month for each HealthPASS enrollee under a total enrollment figure of 88,125. Since total enrollment has averaged 80,342 in the first 3 full months of operation, HMA stands to gain over $378,000 for that period due to this contract provision.

When asked to explain this provision, DPW officials could provide no documentation or specifics on how this contract provision was negotiated. One official seemed pleased that DPW did not have to pay the entire capitation fee for the non-existent Medicaid recipients.

Without documentation, we could not determine DPW's rationale behind this contract provision. We noted that HealthPASS enrollment has not reached the 88,125 figure since October 1988 and that enrollment has been declining since August 1988. The current enrollment trend (preliminary data for September 1989 shows an enrollment of 79,617 recipients) continues downward. Even if this trend stabilizes and enrollment remains at the current level, HMA stands to gain about $6.9 million over the life of the contract because of this contract provision.

Administrative Costs Allowed

The PHC, the previous contractor, received 15 percent of the monthly capitation fee for administrative costs. The PHC, however, had to pay the primary care physicians (PCP's) from the reimbursement received for administrative costs. The PCP payments averaged about $700,000 per month.

The HMA receives 12.3 percent of the monthly capitation fee for administrative costs. On the surface, this appears to be a significant reduction in the rate allowed HMA. In reality, however, it is just the opposite because HMA does not pay PCPs from the administrative costs reimbursed under the contract. The PCPs, like other providers, are paid out of the trust fund established by DPW for that purpose.

Utilizing the capitation payment of $11.5 million for July 1989, we determined that HMA actually received about $389,000 more in reimbursements than PHC would have received. Over the life of the contract, HMA could gain a total of $21.4 million due to this contract provision.

Interest Earned on Trust Fund Deposits

In its proposal, HMA included revenues for interest income of $18,800 per month. This revenue amount was a basis for HMA's proposed capitation fee. The negotiated contract calls for all interest income earned on the principal of the trust fund to be commingled with the trust fund and be payable to HMA quarterly with the approval of DPW. Lack of documentation again prevented us from determining how this contract provision was negotiated. We noted, however, that, it appears to be extremely favorable to HMA.

During the first 2 months of the contract, interest income totaled $80,500, or $61,700 more than what HMA proposed. The HMA stands to gain this entire amount. Over the life of the contract, these extra revenues could reach as high as $1.2 million.

HMA CANNOT SUPPORT COSTS CLAIMED UNDER THE DEVELOPMENTAL CONTRACT

The DPW awarded a developmental contract to HMA on April 6, 1989 for about $1.5 million. As of September 18, 1989, HMA claimed almost $1.2 million under the contract. Since the final cost report had not been submitted to DPW, HMA has the opportunity to submit additional claims.

According to information at DPW, most of the costs claimed by HMA were for consultants, travel and something entitled "allocation". We reviewed these cost centers and found that costs claimed were undocumented, unreasonable and, in some cases extravagant. Internal controls were virtually non-existent.

Consultant Costs

The HMA claimed $658,591 for the costs of consultants. In our opinion, there was insufficient data to support the reasonableness or accuracy of these charges. There were payments made to a total of seven consultants, only one of which had a written agreement with HMA detailing the service they would provide and the cost of each service provided. All other agreements were verbal and in most cases we could not even determine the qualifications of the consultant. In terms of documenting the consultants' charges, the only supporting documentation provided by HMA were invoices submitted by the consultants themselves.

Three examples of what we consider to be undocumented and unallowable charges are as follows.

... HMA paid American Coastal Industries, a firm owned in part by the Chairman of HMA, a total of $89,926 on the basis of a document that stated "for Management Information Systems services". This is inadequate documentation to support the charges to the contract.

... One person was employed to perform consulting services between June 3 and June 30, 1989. The services to be performed reportedly related to community and health care information needed for development of the HealthPASS program. The person was given a fee of $10,000 for this period which comprised 20 normal work days. Assuming that the person worked a full 20 days, the person received $500 per day -- a fee which we consider to be exorbitant. We were unable to determine: how the person was selected; what the person's credentials were that warranted the selection; what specific services the person was selected to perform; and what actual services the person provided to substantiate such a high fee.

... One other person was employed to perform "all Human Resource Activities" associated with the start-up of HealthPASS for the period June 5 to August 31, 1989, at a cost of $200 a day. Here again there was no documentation to support selection, credentials, services supposed to be performed, and services actually performed. The invoice supporting the payment of $3,600 to this person stated that payment was for "services rendered".

Other inconsistencies noted in the consultant category included invoices for services which did not appear to be consultatory services. For example, one charge by Atlantic Systems, Incorporated (part of the joint venture that formed HMA) covered costs of $1,016 for a physician reception at the Hershey Hotel in Philadelphia. Aside from being categorized as a consultant cost, there was no documentation on the detail of the charges or why HMA was billed for 50% of the costs.

Allocation Costs

The HMA claimed $190,000 for "allocation" costs. This consisted of two separate claims -- a $95,000 claim paid to Atlantic Systems, Incorporated and a $95,000 claim paid to Lomax Health Services. The only information available concerning these charges was an August 28, 1989 letter from HMA to DPW. In the letter, HMA explained that the charges encompassed salaries, wages, fringe benefits and other costs which the two companies incurred in preparation to make HMA operational on July 1, 1989. We were unable to obtain adequate documentation to support these costs.

Travel and Transportation Costs

The HMA claimed $71,126 for travel and transportation. According to the contract provisions, these expenses were to be based upon costs incurred not to exceed the Federal Government's General Service Administration's (GSA) Joint Travel Regulations.

The HMA did not have written policies concerning travel and transportation costs. The HMA also had not established internal controls to ensure that travel and transportation charges were proper. Our review showed that travel vouchers were, for the most part, not approved by HMA management and not supported by receipts or other documentation. The documentation, in many instances, consisted of only an invoice or travel expense voucher. In some cases, we were able to determine that some of the costs claimed were definitely not business related. Several examples are listed below.

... $18,959 paid for a planning meeting held at Maho Beach Hotel and Casino Resort located on the Caribbean Island of St. Maarten. Of this amount, $8,079 was paid to Atlantic Systems, Incorporated for hotel accommodations and $10,880 was paid to International Travel Advisors for air travel to and from St. Maarten. The HMA paid the expenses of family members of some HMA officials. The costs for this trip were at first billed to the contract. The entry was later reversed; however, HMA may still bill DPW for costs incurred under the contract since a final cost report has not been submitted.

... $30,029 paid to the Hotel Atop The Bellevue as payment for the period June 29 through July 6, 1989. The contract ended June 30, 1989 and costs incurred after that date should not be charged to this contract. Moreover, this hotel is one of the most expensive in the city and its rates far exceed what is allowable under the GSA regulations. In addition, there was no adequate documentation to support this expenditure.

... $26,851 paid to American International Healthcare for payment of travel costs of their employees. The invoices did not state the reason for the expenditure nor were receipts provided.

... $6,980 paid to International Travel Advisors as payment for airline and train tickets to various locations including Fort Lauderdale, Florida and Chicago, Illinois. The HMA could not provide us with the original receipts for the tickets or any other documentation concerning them except for statements from the travel agency. We noted that $2,286 appeared to be payments for family members of HMA staff during the July 4, 1989 holiday period.

... $1,845 paid to Management Alternatives, Incorporated for new business start-up services. The invoices did not state the reason for this expenditure nor were receipts provided.

Accounting Controls

The HMA had not established adequate accounting controls. Most invoices for costs such as marketing, legal, postage, telephone and, as previously mentioned, consultants, travel and transportation were not approved by HMA management or properly supported by documentation including receipts. This is a material internal control weakness and leads us to conclude that HMA did not have the ability to properly safeguard Federal (contract) funds.

CONCLUSIONS AND RECOMMENDATIONS

In our opinion, DPW has not acted prudently and wisely in the award of the HealthPASS contract. Despite being one of the largest, if not the largest contract ever awarded by the DPW, the award process is noted only for its lack of documentation, and its variance from established contract award procedures.

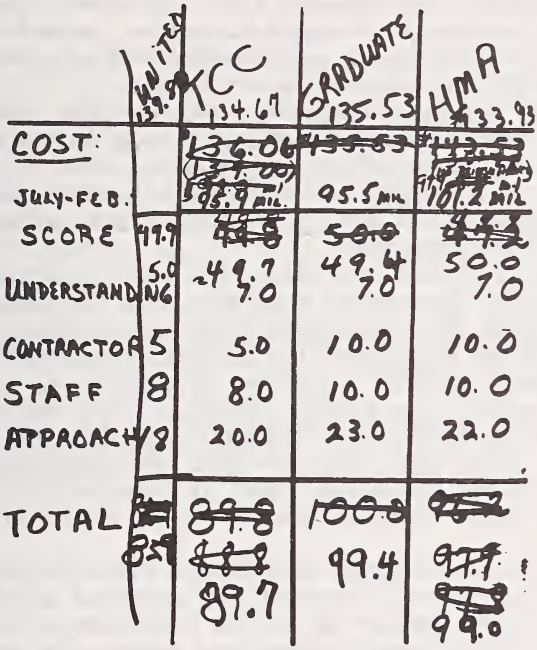
Regardless of the motives of those involved or the competence of the contractor that was ultimately selected through this award process, the cumulative effect of actions taken by DPW over an extended period of time gives the appearance that the basic tenet of public procurement -- fair and open competition --may not have been achieved.

In our opinion, the lack of documentation coupled with actions taken by DPW invite reasonable people to conclude that there was at least the appearance of favoritism in the awarding of the HealthPASS contract. This, together with HMA's demonstrated lack of sensitivity in spending public funds, forces us to conclude that there is insufficient assurance that fair and open competition was achieved and that the best possible contract price was obtained.

We, therefore, recommend, that HCFA not approve the HealthPASS contract with HMA and not approve DPW claims for FFP under the HealthPASS contract and the developmental contract.

Failure to approve this contract should not adversely affect Medicaid recipients currently enrolled. According to information obtained from DPW during our earlier monitoring of the change in contractors, 3 days would be required to convert all HealthPASS enrollees to the regular Medicaid program if such a change becomes necessary. This conversion would generally not require enrollees to search for new physicians or other medical providers because, again according to DPW, many HealthPASS providers also participate in the regular Medicaid program.

Attachment A



	UNITED 139.8	KCC 134.67	GRADUATE 135.53	HMA $133.93
COST:		~~136.06~~ ~~(137.00)~~	~~135.53~~	~~$143.53~~ ~~[illegible]~~
JULY-FEB.		95.9 MIL.	95.5 MIL	101.2 MIL
SCORE	49.9	~~[illegible]~~ 49.7	~~50.0~~ 49.4	~~[illegible]~~ 50.0
UNDERSTANDING	5.0	7.0	7.0	7.0
CONTRACTOR	5	5.0	10.0	10.0
STAFF	8	8.0	10.0	10.0
APPROACH	18	20.0	23.0	22.0
TOTAL	[illegible] 85	~~89.8~~ ~~88.8~~ 89.7	~~100.0~~ 99.4	~~[illegible]~~ ~~97.7~~ ~~[illegible]~~ 99.0

Mr. Towns. Thank you very much.

Ms. Melden.

STATEMENT OF MICHELE MELDEN

Ms. Melden. I want to thank you for inviting us to testify today. I am staff attorney for the National Health Law Program. We were invited to testify because our work involves contract with Medicaid beneficiaries and their lawyers from all over the country, and we have been actively involved in monitoring Medicaid-managed care programs for the past decade.

The subcommittee asked us to address the present administration's stated intent to relax two of the most important protections for clients in managed care programs.

These are, first, the right to enroll voluntarily and disenroll voluntarily. And, two, the right to be enrolled along nonpoor, non-Medicaid enrollees. In our experience of working with beneficiaries who have been involved in managed care plans, we had had hopes managed care would provide a much needed and improved point of access to the health care system for our clients.

Unfortunately, our experience has been otherwise, and tells us Medicaid beneficiaries are mainly underserved by these plans.

The problems of underservice are reflected both in individual horror stories and in evidence of systemwide underservice. I want to give you a couple of examples of the kind of stories that we hear about on a fairly routine basis.

One was from a woman in Philadelphia who had breast cancer. She was authorized for surgical treatment, but after being admitted to the hospital for preop procedures, was suddenly told the treatment would not be covered. The problem was straightened out only after the intervention of a legal services attorney.

We got another call from a teenaged girl in Utah who had a cleft palate. She was authorized for treatment and the treatment was performed, but after that she was told the remaining surgery would not be covered. These may seem like isolated examples, but are not; instead, these examples are evidence of a pattern of underservice.

A recent study of the Dayton Area Health Plan's reports showed infant mortality rates had increased and increased at a rate that exceeded the national average for similar population groups.

Studies of the demonstration sites have shown, also, inadequate levels of prenatal care and immunizations at all sites. Another study in all 30 States found inadequate financing of maternity care throughout.

What is the problem for Medicaid recipients in these plans? First, capitation. Capitation introduces a conflict in the physician-client relationship. The physician must choose by providing care and take a financial loss by doing so. The extent to which that impinges on a physician-client relationship depends on the level of financing and the capitation rate.

Unfortunately, the Medicaid experience nationwide has shown consistent underfinancing. Typically, States set capitation levels at 90 to 95 percent of Medicaid service fee for rates. They are doing this because they are trying to save capitation.

This is a problem, because as we know, the existing Medicaid programs are already underfunded, and this is evidenced by the serious shortage of physicians willing to accept Medicaid beneficiaries.

However, a further problem and a difference here is when managed care plans underserve, the States and Federal Government are literally throwing their money away, because the providers are taking the money, even though care frequently is not being provided.

In addition, the problem in managed care programs nationwide has been that States simply are not doing their jobs in monitoring the quality of the care being provided. They are not gathering useful data and taking other necessary steps to detect underservice.

Finally, these plans overall have not attracted new providers. The studies will show access really has not been expanded, because the plans are using existing providers to accept Medicaid. This raises the serious risk that States are irresponsibly pulling in the inadequate, unscrupulous practitioners who make up the so-called Medicaid mills, because they are taking advantage of the dollars available through prepared capitation rates.

Therefore, we cannot overemphasize the importance of two quality safeguards: Voluntary enrollment and mixed enrollment. With voluntary enrollment, participants can vote with their feet. They can protect themselves when their health is being put at risk with underservice.

With mixed enrollment, the plants are forced to compete with middle class clientele. It forces these businesses to prove themselves in the private market, protecting against their exploitation of scarce Government revenue.

I want to thank the subcommittee for inviting us here today.

[Testimony resumes on p. 453.]

[The prepared statement of Ms. Melden follows:]

Testimony Presented by

Michele Melden, Staff Attorney

National Health Law Program

The Subcommittee on Health and the Environment has invited the National Health Law Program to address the Bush Administration's stated intent to expand use of managed care for Medicaid recipients by relaxing existing freedom of choice and enrollment protections. The Subcommittee has also requested that we present any current problems with existing Medicaid managed care programs.

The National Health Law Program, Inc., (NHeLP), is a health law support center that provides professional advice and assistance to legal services advocates and their clients. We have extensive and ongoing contact with poor people and their representatives throughout the country regarding a variety of health subjects, including Medicaid, which are of vital concern to them. Over the past decade, NHeLP has been actively involved in the issue of managed care and its effects on Medicaid recipients nationwide.

Based on our experience, we urge this Subcommittee to reject any attempts to expand use of managed care and to reject this Administration's stated intent to abandon two vital protections for our clients -- namely, enrollment should be voluntary, and Medicaid recipients should be enrolled alongside non-poor, non-Medicaid recipients.

I. Introduction

Managed health care can be defined in many ways, one of which is a system that provides access to a range of needed services that are coordinated and monitored by a specific, appropriate health care manager. However, most forms of managed health care also contemplate use of capitation, a reimbursement method by which prepayment is made to cover a given patient or patient group's health care needs. Capitation is used as an incentive to discourage overutilization of unnecessary services. Therefore, managed care coupled with capitation is principally a device used to control costs.

In states' implementation of managed care for Medicaid recipients, many problems have resulted in programs using capitation. This testimony will address itself principally to the relationship between capitation as an incentive toward underservice and the special problems with this incentive mechanism for Medicaid recipients.

Because experience has shown that capitation poses significant risks to Medicaid recipients, protecting recipients' freedom to choose between managed care and fee-for-service care, and instituting requirements that Medicaid recipients be enrolled alongside non-poor, non-Medicaid recipients, are essential to offset and compensate for the risks posed by capitation. In addition, a number of other safeguards should be added in order to rectify the problems posed by existing Medicaid managed care programs.

II. The effects of capitation

Capitation is a mechanism for paying an organization a set amount in advance to provide for the anticipated health care needs of a given group of patients. As used in managed care programs, capitation is supposed to institute incentives against overutilization of unnecessary services. The belief is that additional controls on utilization will result in greater efficiencies. In fact, proponents believe the incentives to save even will improve care because providers will be encouraged to devote more resources to preventive and primary care, and to coordinating care.

Capitation must be contrasted to "fee-for-service" care. Under "fee-for-service" care, physicians are paid each time they provide care. Typically, an outside third party pays for this care, such as an insurance company, and this outside party takes on the risk of paying for care provided to a given patient group. Under this system, the physician is not placed at any financial risk; only the payor is at risk. In contrast, under capitation, the managed care plan, which is responsible for providing the care, is paid in advance to provide care to a given patient group. Therefore, the provider is placed at risk for the amount of care required. The provider thus doubles up as a type of "insurer" and a provider. The extent to which the provider is placed at financial risk will affect the amount of care provided.

Many managed care plans translate their financial risks into risks imposed on the physicians as well. According to a recent study in the New England Journal of Medicine, the vast majority of health maintenance organizations (HMOs) impose financial incentives on physicians to control costs. These consist of: a) the HMO withholding income, and if the physician or the group comes out with a deficit, the HMO will retain the funds; b) imposing financial penalties on physicians for deficits that exceed the withheld amounts; c) requiring physicians to pay directly for laboratory and specialty referrals; and d) offering bonuses to physicians who spend less than the group average.[1] These incentive mechanisms are often reinforced with rigorous peer review for overutilization.

One scholar, Bruce Spitz, who has studied these systems, has criticized this use of physicians as "small insurance companies," because these mechanisms place the physician in an "adversarial and pernicious" relationship with the patient.[2] Indeed, a study appearing in the July 1989 issue of the New England Journal of Medicine documented that financial disincentives to serve will result in less service.[3]

In theory, the pressures posed by capitation are only supposed to encourage more "efficient" practice. However, the extent to which the capitated levels are inadequate to meet a patient group's needs will tip the balance toward underservice.

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[1] Hillman, "Special Report: Financial Incentives for Physicians in HMOs," 317 New Eng. J. Med. 1743 (Dec. 31, 1987).

[2] Spitz & Abramson, "Competition, Capitation, and Case Management," 65 Milbank Quarterly 348, 360 (1987).

[3] Hillman, Pauley, Kerstein, "How Do Financial Incentives Affect Physicians' Clinical Decisions and the Financial Performance of Health Maintenance Organizations?" 321 New Eng. J. Med. 86 (July 31, 1989).

III. The Medicaid Experience

Experience throughout the states has demonstrated that use of capitated managed care for Medicaid recipients has not resulted in more efficient or better care. Instead, managed care programs that serve Medicaid recipients often have institutionalized incentives to underserve a population already suffering grossly inadequate access. Indeed, we must determine whether, in the cases that "savings" are realized, these savings have resulted in worsened care to the already underserved. If so, there is no justification for shifting the limited dollars states are allocating for Medicaid recipients to the additional layers of bureaucracy, administration, and profit-taking involved in using managed care systems.

A. Underfinancing

Experience has shown that the use of capitation as an incentive to underserve is compromising the quality of care Medicaid recipients receive. The principal reason for this is that the capitated rates used in Medicaid managed care programs are based on a presumption that less must be spent on managed care than is spent in states' Medicaid fee-for-service system.[4] In most states, the capitated rates are set at 90-95% of the Medicaid program's fee-for-service rates.[5] However, most states' Medicaid fee-for-service rates are highly underfinanced.[6] This underfinancing in the Medicaid system is directly related to a shortage of physicians willing to accept the Medicaid rates, and therefore, a shortage of physicians willing to treat Medicaid recipients.[7]

Requiring that managed care achieve cost-savings that justify themselves in relation to the existing underfinanced Medicaid system will result in continued underfinancing which aggravates the managed care programs' incentives to underserve. This underfinancing raises the danger that managed care will replicate Medicaid's currently inadequate provider participation. The principal difference between managed care and fee-for-services, however, is that managed care programs will be taking funds and not providing care, while fee-for-service physicians are not paid when rejecting inadequate Medicaid rates.

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[4] Spitz & Abramson, supra, 355-57; Anderson & Fox, "Lessons Learned from Medicaid Managed Care Approaches," Health Affairs 71, 80 (Spring 1987).

[5] Id.

[6] Id.

[7] See Perkins, "Increasing Provider Participation in the Medicaid Program: Is There a Doctor in the House?" 26 Hous.L.Rev. 77 (1989).

B. Inability to meet Medicaid clients' needs

We should be particularly concerned about putting people covered by Medicaid at risk through underservice. Most Medicaid recipients are low-income women and children, and disabled individuals. Both of these groups have high health care needs and therefore, are placed at high risk by inadequate access. For example, low-income pregnant women are at least twice as likely as higher-income women to have a child die within the first year of birth. This high infant mortality rate is due primarily to inadequate prenatal care. In addition, the maternal mortality rates for black and other non-white women is four times as high as for white women; and low-income children are two times as likely to suffer long-term disability at birth, in major part because of a higher risk of low-birth weight. These statistics show that any disincentives to providing this population health care, and any barriers to their receiving care, could result in more infant and maternal deaths, and more disabilities.

Managed care plans' purported ability to save costs may not apply to a population with high health care needs. There is considerable evidence that managed care programs that serve the non-Medicaid population engage in "skimming" -- that is, they market to and enroll a disproportionately healthy group of people.[8] In fact, studies on disenrollment for managed care plans demonstrate that when people become unhealthy, they are more likely to become dissatisfied with a managed care plan, and therefore are more likely to disenroll.[9]

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[8] Anderson & Fox, supra, at 81; Strumwasser, Pasanjpe, Ronis, McGinnis, Kee, Hall, "The Triple Option Choice: Self-Selection Bias in Traditional Coverage, HMOs, and PPOs," 26 Inquiry 432 (Winter 1989).

Indeed, studies of Medicaid managed care programs have shown that these plans were unable to meet the special needs of high-risk pregnant women and children, or of patients with chronic needs.[10] According to a 1989 study of the Medicaid Demonstration projects, the amount and timeliness of prenatal care were inadequate at all sites.[11] Most women did not receive any prenatal care until their second trimester of pregnancy; and the average number of prenatal visits at all sites was less than 8, far fewer than the 12 prenatal visits recommended by the American College of Obstetrics and Gynecology. In addition, immunizations for children were inadequate at all sites. These findings were consistent with a 1987 study of Medicaid managed care plans in 30 states which found that capitation levels for maternity care were seriously underfinanced throughout the programs.[12]

These studies also are consistent with reports from advocates across the country. For example, in analyzing Ohio State's 1989 quarterly reports on the Dayton Area Health Plan, a mandatory Medicaid managed care program for AFDC recipients, the Legal Aid Society of Dayton found that only 12% of eligible children were provided mandatory EPSDT services, and the referral rates were one-third or less the national rates reported for referable conditions. According to Bruce Spitz, who studied these figures, these rates are "scandalously low."[13]

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[9] DesHarnais, "Enrollment In and Disenrollment From Health Maintenance Organizations by Medicaid Recipients," 6 Health Care Financing Review 39 (Spring 1985) (showing higher than average utilization during three months following disenrollment).

[10] See Freund, Rossiter, Fox, Meyer, Hurley, Carey & Paul, "Evaluation of the Medicaid Competition Demonstrations," 11 Health Care Financing Review 81 (Winter 1989); Anderson & Fox, supra.

[11] Freund, Rossiter, Fox, supra.

[12] Rosenbaum, Hughes, Butler & Howard, "Incantations in the Dark: Medicaid Managed Care and Maternity Care," 66 Milbank Quarterly 661, 685 (1989).

In addition, not only do studies and reports show that many of these programs failed to provide early and continuous prenatal and pediatric care, but also they have failed to meet the needs of patients with chronic health conditions.[14] This may be due to their lack of experience with patients who have high health care needs. These inadequacies also may be due to rapid implementation of the programs and the fact that these recipients' special needs make them particularly vulnerable to incentives directed toward underservice. For example, the Santa Barbara Health Initiative, in California, has enrolled a large population of disabled individuals, many of whom must rely on specialized orthopedic care to meet their primary needs. However, the program limits disabled enrollees' access to specialty providers to a hospital clinic that employs only medical school residents who rotate through the clinic one day a week. This prevents any continuous care which is essential to meeting the health care needs of these disabled recipients who have chronic conditions.

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[13] Bruce Spitz's letter analyzing these figures is available from NHeLP.

[14] See Anderson & Fox, supra.

Other managed care programs rely similarly on medical school residents in hospital clinics to deliver care. For example, in Philadelphia, the providers listed on many recipients' cards are the doctors who supervise at the teaching hospitals' clinics. However, recipients must wait a minimum of four weeks to see the named provider, and most, therefore, obtain their care instead from the medical students. Again, this results in a lack of continuity of care, as well as inadequate quality.

C. Inappropriate Delays and Denials

Most managed care programs use "gatekeepers" to control utilization. A "gatekeeper" is usually a primary care physician who determines whether a patient should see a specialist or obtain particular services, such as laboratory testing. In theory, managed care systems are supposed to encourage physicians to provide preventive and primary care in order to avoid the high costs of inappropriate specialty or emergency care.

In adopting the use of a gatekeeper system, there is a presumption that the cost of care is too high because of overuse of specialty care. Either the patient is seeking or the provider is providing specialty care inappropriately. There is, however, a significant question as to whether this presumption applies to Medicaid recipients.

There is a great deal of research and documentation demonstrating that for the most part, Medicaid recipients are unable to find physicians willing to accept Medicaid because the rates are abysmally low.[15] The Medicaid rates are typically set in relation to states' budgetary constraints, and are therefore hugely discounted below the private-pay rate. In the competition between Medicaid and private-pay patients, Medicaid patients have come out the clear losers. Therefore, because of inadequate access to preventive and primary care, presumptions about Medicaid clients' overutilization are not applicable. Instead, Medicaid recipients have been forced to rely on emergency services, which are much more costly, especially once their health has declined substantially, because they have inadequate access in the fee-for-service system.

Medicaid managed care programs have not, however, fulfilled their promise of providing expanded preventive and primary care, which are necessary to offset the need for emergency care. Indeed, strict use of "gatekeepers" has resulted in inappropriate delays and denials to primary care. Reports from advocates nationwide reflect patterns of denials and delays for basic preventive and primary services.

For example, an advocate in Pennsylvania reported that a woman receiving treatment for breast cancer was inappropriately denied approval for surgery after already being admitted to the hospital for pre-operative procedures. The problem was straightened out only after a Legal Services attorney intervened.

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[15] _See_ Perkins, _supra_.

Another advocate in Utah reported that a client requiring dental surgery for a cleft palate, and for whom the preliminary surgical treatment had been performed, was abruptly terminated from services when the managed care plan inappropriately denied payment based on a procedural error caused by the participating provider's confusion over how to obtain prior approval.

During the Santa Barbara Health Initiative's first few years of operation, some women waited over two years for gynecological examinations. In addition, one family served by the Santa Barbara Health Initiative, who has received approval for their daughter to see a pediatric orthopedist, has waited nine months for the program to identify a particular specialist for approval, and is still waiting.

Unfortunately, managed care plans' incentives against overutilization are not counterbalanced with incentives that reward coordinated and follow-up services. Furthermore, states are not taking sufficient steps to monitor the quality of care provided, or to detect patterns of underservice.

It is also ironic that to the extent that Medicaid recipients have been limited to receiving expensive emergency room services in the fee-for-service system, managed care plans have been successful at blocking even this limited access, while failing to fulfill their promise to provide preventive, primary care. For example, a report prepared by the emergency pediatric department at Children's Hospital of Philadelphia studied the follow-up care given to children denied approval for emergency care by HealthPass, a Pennsylvania Medicaid managed care program.[16] The report offered several examples of inappropriate denials. One such example was a two-month old infant who was turned away only to return a few hours later with a respiratory arrest; another example was a child who came with a fever of 104 degrees fahrenheit, and upon being rejected for coverage by the managed care plan, suffered a seizure before leaving the building and required an endotracheal intubation. After Children's Hospital had completed its six-month study of HealthPass's treatment of pediatric emergencies, it decided to treat all children who presented themselves to the emergency room, whether or not HealthPass approved the care, unless the child could be assured of seeing a primary care physician immediately.

HealthPass, like many other Medicaid managed care programs, had adopted a system whereby emergency care was not approved unless the patient was suffering from a "life-threatening" emergency. Such a determination is difficult to make unless a physician actually performs a physical examination. However, as in many Medicaid managed care programs, the HMO would not approve even the physical examination unless the patient already was determined to be suffering from a "life-threatening" emergency.

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[16] Shaw, Selbst & Gill, "Indigent Children Who are Denied Care in the Emergency Department," prepared by the Children's Hospital of Philadelphia, July 31, 1989 (available from NHeLP).

Nonmedical personnel at the HMO often made these decisions, relying solely on information communicated by an emergency room clerk.

Inappropriate emergency room denials are rampant across Medicaid managed care plans throughout the country. For example, a Chicago advocate reported a client whose child came to an emergency room covered with burns. The HMO refused coverage and instead, called in the child for an appointment. When the HMO physician did not show up for the scheduled appointment, the parents returned to another local hospital emergency room that accepted the child despite the HMO's stated refusal to cover services.

Advocates have also reported inappropriate denials for other services that tend to be expensive, such as for drug and alcohol treatment. For example, in Pennsylvania, HealthPass was consistently denying approval for drug and alcohol treatment for pregnant women or women with children. Some of these same recipients were lucky enough to get admitted to programs outside the HMO, but had to establish their residence outside of the geographic area mandatorily covered by the HMO. However, the process of disenrollment took a minimum of two months, serving as a substantial disincentive to recipients eligible for these needed services.

D. Institutional barriers

In reality, many managed care programs, including Medicaid managed care programs, do not rely principally on the "gatekeeper" or primary care physician to deny care in order to control utilization, but rather, rely on institutional barriers which function equally well, if not better, to limit access. These include long telephone waiting periods to make appointments, delays in making specialty referrals, and limited as well as lengthy internal review procedures for denials. These barriers are particularly dangerous to Medicaid recipients because of their high health care needs.

In addition, low-income individuals have more trouble overcoming these barriers due to conditions related to poverty and the lack of disposable income to fill in the gaps. For example, a person unable to afford a telephone cannot sit for long periods of time on the telephone to schedule appointments. Recipients may not be able to reach HMOs or follow up referrals to specialty care because providers are located in areas difficult to reach by public transportation. Without disposable income, recipients cannot afford second opinions in order to challenge denials.

Indeed, a study by the Rand Corporation, appearing in the May 1986 issue of Lancet, found that in comparing the health outcomes of lower-income people inside and outside HMOs, lower-income people in HMOs experienced significantly worsened health results than lower-income people using fee-for-service care, including more hospital days, and greater risks of dying. In addition, lower-income people in HMOs came out with significantly worsened health results than middle-income people in HMOs. The report postulated that the worsened health results were related to the combination of HMOs' predisposition to underserve with the following barriers used by HMOs to delay and deny care: a) telephone-based queueing systems for scheduling appointments; b) restrictions on the use of accident and emergency departments; and c) greater difficulties in arranging transportation.

These institutional barriers also translate into bureaucratic mazes that can pose the most significant barriers to access when combined with Medicaid's own bureaucracy. As one advocate in Pennsylvania noted, most of the problems faced by Medicaid clients relate either to recipients' or providers' confusion about how to verify eligibility and obtain approval. Therefore, it is not uncommon to find recipients have been inappropriately disenrolled, or are not enrolled in a timely manner, or are denied coverage inappropriately because providers are confused about how to obtain prior authorization. On the surface, most of these problems relate to "paperwork," but in reality, reflect a pattern behind which the most flimsy excuses are proffered to justify the HMOs' refusal to cover appropriate services. This pattern is consistent with the incentives toward underutilization, which are aggravated by underfinancing.

IV. Question of expanding access

One argument offered in favor of managed care is that it expands access to recipients who otherwise could not find providers at all. However, nationwide experience has shown that when states institute managed care plans, they do not expand access, but rather, the same providers who served the Medicaid population continue to do so.[17]

In a study of the demonstration projects, only one had utilized an existing HMO that was serving a non-Medicaid population.[18] The remaining six projects had failed to attract new physicians to Medicaid and instead, had relied on traditional Medicaid providers -- that is, hospitals, physicians, and neighborhood health centers. The report concluded that expanding use of managed care will not improve access to a broader array of mainstream physicians, and therefore, the danger remains of relegating Medicaid recipients to the bottom tier of available medical care.

V. Is this a wise use of limited Medicaid dollars?

We must analyze closely the health risks faced by Medicaid clients when the state passes on the financial risks of providing care to high-need patients at inadequate capitation levels. In the last two years, the managed care industry has lost $900 million per year. According to an April 1990 report in the The New Physician, the vast majority of HMOs that lost money in the last five years were "individual practice associations" (IPAs);

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[17] Anderson & Fox, supra, at 83; Freund, Rossiter, Fox, supra, at 95.

[18] Anderson & Fox, supra, at 83.

the majority of HMOs serving Medicaid recipients are IPAs.[19] At the same time, the extent to which HMOs have been able to operate without a loss may be related in large part to the fact that they serve a predominantly healthy population group, far healthier than most Medicaid recipients.

Some scholars have pointed out managed care rates for Medicaid recipients must be based on the Medicaid population's unique needs, and not on the HMOs' experience with disproportionately healthy populations.[20] If the rates are not adequate, the danger is Medicaid clients will be at increased risk of underservice. However, if managed care is viewed as a cost-savings mechanism, then it will be politically infeasible to set adequate rates.

The financial risks created by replicating inadequate access is that states may be forced to spend more anyway, because recipients will be forced to rely on emergency room care after their health has declined substantially. Therefore, in order for states to realize cost-savings on this population in the long term, they should be prepared to spend more on preventive and primary care than they spend presently, which means they must not base capitation levels on the existing Medicaid fee-for-service experience.

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[19] "Cost-Containment in Public Programs," Intergovernmental Health Policy Project (March 1990).

[20] Freund, Rossiter, Fox, supra, at 91; Anderson & Fox, supra, at 80-81.

States also must factor in additional administrative costs that will be incurred both by the managed care plans and by the states. The states must be able to address the varied enrollment systems and institute procedures for reviewing the plans' utilization controls. A report reviewing Milwaukee's managed care plan pointed out that the state's savings were offset by the administrative costs involved in monitoring HMO quality and utilization controls.[21] Indeed, the report was highly critical of the state's failure to spend the amounts necessary to gather usable date to monitor utilization and detect inadequate care.

It is not clear that the cost-savings justify additional administrative costs. In a study of four demonstration sites, no clear pattern was established that utilization changes were directly translatable into program savings.[22] According to a 1985 report on Citicare, a Kentucky managed care program used to serve Medicaid recipients, the program spent 14.2% of its revenues on profit and administrative costs, while the Medicaid agency only had spent 4.4% on administrative costs.[23] One Washington Medicaid managed care program paid an administrative agency over $360,000 to run a system expected to generate $65,000 in savings.[24] Whatever "efficiencies" are derived through capitation do not justify this cost-shifting. In fact, one of the reasons why California's Expanded Choice proposal was not adopted in San Diego was that the state concluded that the extra costs involved in prepaying the HMO, and thereby forfeiting the interest that could be earned by paying retrospectively for care, would not offset the cost-savings.

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[21] Rowland & Lyons, "Mandatory HMO Care for Milwaukee's Poor," Health Affairs 87 (Spring 1987).

[22] See Freund & Neuschler, "Overview of Medicaid Capitation and Case-Management Initiatives," Health Care Financing Review 81, 89 (1986 Annual Supplement).

[23] National Health Law Program, An Advocate's Guide to Medicaid Case Management Systems at 80 n.539 (1989).

VI. The importance of quality safeguards

The present administration's stated plan to relax freedom of choice and mixed enrollment protections threatens to compromise Medicaid enrollees' already fragile position within managed care plans. Mandatory enrollment will turn the Medicaid population into a captive base for the profit-taking motives of the managed care plans. Without the freedom to choose between managed care plans and fee-for-service physicians, Medicaid recipients will not be able to express their dissatisfaction by disenrolling, and the plans will not be forced to compete for their enrollment.

This lack of accountability will be aggravated further by a relaxation of the requirement that managed care plans that serve Medicaid recipients also enroll at least 25% non-Medicaid and non-Medicare recipients.[25] Without mixed enrollment requirements, the plans will not be forced to compete for middle-income clientele. This is likely to result in all kinds of unscrupulous practices, as evidenced by the California experience in the 1970s, where many entities arrived on the scene merely for profit-taking, seeking to exploit "the margin between capitation payments and expenses for services rendered."[26]

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[24] Id. at 80.

[25] The 25% non-Medicaid and non-Medicare population also should not include other poor enrollees. A federal court recently struck down the Health Care Financing Administration's approval for Ohio to include general assistance recipients in this 25% population. Oglesby v. Berry, C-3-89-125 (W.D.Ohio, Nov. 17, 1989) (consent

Congress is aware that increased vigilance has been necessary to assure Medicaid managed care enrollees are not underserved. For example, in 1987, Congress passed a number of changes to the HMO Act which increased civil penalties against managed care plans that fail substantially to provide medically necessary services and items required under Medicaid.[27] However, reliance on civil penalties to respond only to the most egregious violations is insufficient to balance recipients' needs to "vote with their feet." Forcing these managed care programs to remain competitive in relation to both the Medicaid and the non-Medicaid population is a much better and more efficient safety valve to safeguard the quality of care recipients receive.

In addition, Congress should be wary of any attempts to bring about a rapid expansion in the use of managed care programs. Recent Medicaid managed care experience has shown that

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decree).

[26] D'Onofrio & Mullen, "Consumer Problems with Prepaid Health Plans in California," 92 Public Health Reports 121, 124 (April 1977).

[27] See Pub. L. 100-360, § 411(k)(12) ("Medicare Catastrophic Coverage Act of 1988).

expanding managed care will not result in new providers participating in Medicaid, but instead, in already participating providers being converted into groups accepting the prepayment amounts. Indeed, one has to worry whether a rapid expansion of the use of managed care systems will result in those providers who already are providing inadequate care, those that make up the so-called "Medicaid mills," capitalizing on the profit-taking available through managed care plans. Therefore, implementation of new programs must be planned carefully. Indeed, according to some studies, at least two years is required for each plan to make sure that the confusion regarding enrollment and cost-controls is minimized.[28]

VII. Conclusion

By capping amounts that states will pay to serve Medicaid clients, states are in effect rationing the care to be provided. However, through the use of managed care plans and capitation, states are delegating responsibility for these rationing decisions to the providers accepting the financial risks involved with capitation. Unfortunately, these disincentives against overuse have not been accompanied by incentives to follow protocols that promote primary, preventive, and coordinated care. Just at the time when coverage obligations are expanding toward more comprehensive care for pregnant women, infants, and children, expanded use of managed care programs threatens to undercut these needed improvements.

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[28] Freund, "The Private Delivery of Medicaid Services: Lessons from Administrators, Providers and Policy Makers," 9 J. of Ambulatory Care Mgmt. 54 (1986).

A number of studies have improved our knowledge about how to bring down unconscionably high maternal and infant death and disability rates. High-risk mothers and children require early, stable, and continuous enrollment; adequate reimbursement; mechanisms for providing follow-up services so that care remains continuous; and health education. This care is likely to cost more than states have been prepared to spend in the past, although the costs of caring for low-birth weight and disabled infants may be substantially reduced. Nonetheless, the fact is that we do not yet have adequate information on exactly how much the states must spend to do a good job in this area because states have not yet spent at necessary levels. Therefore, any methods by which capitation levels are measured against past Medicaid experience will be faulty.

If any expanded use of managed care plans is contemplated, we urge that states be required to make enrollment voluntary, and that managed care plans be required to enroll Medicaid recipients alongside non-poor, non-Medicaid recipients. States should not be permitted to base the capitated rates on already inadequate Medicaid fee-for-service rates. In addition, states should be required to proceed gradually in order to ensure the managed care plans with which states contract can prove they are solid financially and can deliver care responsibly, and to determine whether the cost-savings justify additional administrative costs, incurred both by the plans and the states.

Mr. Towns. Ms. Hill.

STATEMENT OF BARBARA HILL

Ms. Hill. Thank you, Mr. Chairman.

My name again is Barbara Hill, I am president of the Johns Hopkins Health Plan, which is a federally qualified, nonprofit IPA model HMO, serving 100,000 members, one-fifth of whom are Medicaid recipients.

I am also a member of the board of directors of the Group Health Association of America, the Nation's oldest and largest trade association for HMO's, and I serve as vice chairman of GHA subcommittee. With me is David Siegel, medical director for the Health Alliance Plan of Michigan. HAP is a nonprofit mixed model HMO serving almost 400,000 members.

We have been asked to testify today about HMO participation in the Medicaid program, and I would like first to give a few facts of the status of that participation.

In 1988, figures from HCFA show only 127 HMO's in the United States participate in the Medicaid program. That is about one-fourth. While virtually every State has HMO's, only 28 State Medicaid agencies contract with HMO's to care for Medicaid recipients. The outcome of that is only 850,000 Medicaid recipients receive their care through HMO's. In other words, less than 5 percent.

This relatively low participation is unfortunate for two reasons: First of all, we believe the HMO's offer services and quality of care not available on the fee-for-service side. The fee-for-service delivery system is episodic in nature, and often dependent on emergency rooms.

It is unfortunate, because the HMO's offer automatic savings to the State and Federal Government, because the HMO's are capitated usually at a rate less than the fee-for-service equivalent.

There are two barriers to prevent HMO's from participating in the Medicaid program. The marketing issues have been discussed at length at other times in this subcommittee, so I would like to take the time to focus, instead, on the issues relating to reimbursement rates, and the recommendations GHAA would like to offer.

The problems with reimbursement focus around the fact reimbursement rates are set almost totally at the discretion of the 50 States. The only limit placed on them by the Federal Government is those rates may not exceed 100 percent of the fee-for-service equivalent.

Usually, they are paid as low as 90 percent of the fee-for-service equivalent, and out of that money, they have to pay not only for the cost of medical care but also for cost of claims processing, administration and marketing. Valuable Medicare dollars are going out for those expenses.

Our recommendations are discussed at length in our written testimony, but I would like to offer some here. These are recommendations we see as being low cost or no cost.

First of all, we recommend an expansion of the rights which are now available only to federally qualified HMO's. Our reason for that is many HMO's have ceased applying for Federal qualification. State regulations have gotten much tighter, and much more uniform.

Those rights specifically are the guarantee of eligibility for a 6-month period, and the decrease of the rights of Medicaid recipients to disenroll for a 6-month period. We also recommend the automatic reenrollment or enrolling eligibility guarantee of 3 months. This proposal is to help with the problem of Medicaid recipients who lose their Medicaid eligibility for a short period because they fail to recertify.

When they go back to do so, they have lost their HMO enrollment. We also propose allowing the exemption to 75–25 enrollments to public HMO's who have often exhausted all their efforts to enroll members from the commercial program.

We recommend extending that to HMO medically underserved areas. Obviously, in order to make these exemptions, the appropriate quality assurance and fiscal solvency guarantees would have to be in place.

We recommend rates offered to Medicaid HMO's must be actuarily certified. Right now, rates are developed on the State level by individual State budget agencies, and actuarial certification would give HMO's some confidence the rates were sound.

We propose those rates include administrative cost allowance, so medical dollars need not be rerouted to pay for the claim processing and administrative cost. We recommend alternative rate approaches.

On the subject of physicians' incentives and quality assurance discussed in length in the GAO report, our written testimony addresses those issues in length, and Dr. Siegel would be happy to answer any questions.

Suffice it to say, we are disappointed in the recommendations of the GAO report. We believe managed care offers Medicaid recipients quality care with easy access, personalized attention and focus on wellness and prevention, which is not available in the fee-for-service side.

Many HMO's have a strong commitment to Medicaid recipients and want to be active in serving that population, but they find it to be a frustrating experience. We need your help and believe the recommendations we have made are a small step in the right direction towards eliminating some of these problems and creating a better environment to encourage others to participate.

The GHAA looks forward to working with you, Mr. Chairman, and members of the subcommittee, and we thank you for the opportunity to participate.

[Testimony resumes on p. 478.]

[The prepared statement of Ms. Hill follows:]

TESTIMONY ON

HMO PARTICIPATION IN MEDICAID

FOR THE

GROUP HEALTH ASSOCIATION OF AMERICA, INC.

by

BARBARA HILL

Good morning Mr. Chairman and members of the Subcommittee, my name is Barbara Hill. I am President of the Johns Hopkins Health Plan, a non-profit federally qualified independent practice association (IPA) model health maintenance organization (HMO). Our total enrollment is 99,000, of which 22,000 are Medicaid beneficiaries. I am a member of the Group Health Association of America's (GHAA's) Board of Directors and I have served as vice chairman of the GHAA Subcommittee on Medicaid and the Uninsured. I am accompanied today by Dr. David Siegel, Medical Director for the Health Alliance Plan (HAP) of Michigan. HAP is a non-profit mixed model HMO serving nearly 398,088 enrollees and 8,497 are Medicaid beneficiaries.

I appear hear today on behalf of GHAA, the oldest and largest trade association for HMOs in the United States. GHAA's member organizations serve approximately 75 percent of the 35 million people enrolled nationwide in 591 HMOs.

I have been asked today to testify on HMO participation in the Medicaid program. I would like to briefly highlight the nature of HMO participation in this program and then discuss barriers to participation and some recommendations for change.

Over time, HMOs have emerged as a proven mechanism for providing quality, comprehensive health care at an affordable price. HMOs serve to enhance access and coordinate comprehensive care, while increasing the efficiency of an often disjointed health care system.

Because of their integrated systems, HMOs can improve upon the episodic and uncoordinated method in which many Medicaid beneficiaries frequently receive medical care. The HMO emphasis on preventive services such as prenatal and well baby care, can avoid more serious and costly illnesses, and ultimately enhance an individual's economic productivity.

In an era of continuing health care inflation, HMOs also offer government a proven mechanism for encouraging access to quality care at a reasonable price. In many states, the greater efficiency of the HMO system over the fee-for-service system can result in cost containment for the Medicaid program.

HMO Participation in Medicaid

According to the Health Care Financing Administration (HCFA), as of 1988, 127 HMOs participate in the Medicaid program and enroll 850,000 Medicaid beneficiaries, or less than five percent of all Medicaid participants. (These figures do not include prepaid health plans.) This is less than a quarter of all HMOs.

Less than a quarter of the 114 HMOs that indicated to us for GHAA's National Directory of HMOs that they contracted with Medicaid in 1989, 52 of these, or 46%, were GHAA member plans. HMOs are located in almost every state, but currently only 28 state Medicaid departments contract with HMOs.

In April, GHAA conducted a survey of its 52 member plans with Medicaid contracts to gain insight into the nature of HMO participation in the Medicaid program. The purpose of the study was to enable GHAA to provide federal and state government with information concerning HMO satisfaction within the Medicaid program and to identify obstacles to the effective participation of HMOs in the Medicaid program.

On the whole, plans with Medicaid contracts are fairly evenly distributed across HMO model types. Plans with Medicaid contracts are more likely to be older, larger plans -- 40% of the plans with Medicaid contracts have enrollment of 50,000 or more. Over half of the plans with Medicaid contracts are 8 years or older. Finally, those with Medicaid contracts are predominately not-for-profit -- 69%.

Barriers to Participation

In addition to identifying the characteristics of the HMOs that contract with Medicaid, the survey also attempted to identify impediments in the Medicaid program which may effect future HMO participation in the Medicaid program.

Two fundamental problems that limit the effective involvement of HMOs in the Medicaid program were identified - marketing and reimbursement.

Due to the nature of the Medicaid system, marketing an HMO product can be a time-consuming and expensive process. First, states generally cannot provide HMOs with direct access to Medicaid beneficiary names and addresses, so any marketing done by an HMO is largely on an individual basis. This is quite different from how the HMO market functions with respect to the rest of its potential enrollees.

Secondly, since some state's Medicaid programs include comprehensive benefit packages, HMOs cannot offer Medicaid beneficiaries the enhanced benefits or reduced cost sharing which have appealed to commercial enrollees. Therefore, the traditional incentives to Medicaid beneficiaries for enrollment in an HMO are relatively weak.

The welfare system further complicates matters by disenrolling Medicaid beneficiaries as soon as they lose their Medicaid eligibility. For example, it is quite common for Medicaid beneficiaries to lose eligibility for a short period of time due to administrative problems when the individual is being recertified for eligibility. During this period two things happen: the individual loses coverage when he or she actually qualifies for coverage, and the individual must go through the enrollment process all over again as if they were a new applicant.

Marketing is also complicated because unlike commercial enrollment which is annual, Medicaid enrollments are on a day-to-day basis. While this is intended as a beneficiary protection to allow the beneficiary to opt out, this detracts from the ability of an HMO to plan and forecast based on a stable enrollment. It also fails to encourage continuity of care.

Reimbursement to HMOs serving Medicaid beneficiaries is a serious problem and is almost entirely at the discretion of the fifty states. States pay HMOs a capitation rate to provide services to the Medicaid beneficiaries. The only effective restriction on Medicaid HMO capitation levels is that the states cannot pay HMOs more than the cost of serving comparable Medicaid individuals on a fee-for-service basis. In practice, HMOs are typically paid considerably less -- sometimes as much as ten percent less than the equivalent cost of medical services in the fee-for-service sector. Yet, in addition to providing medical care for the capitation, HMOs must also pay for a number of other services -- including the high cost of marketing, claims processing, utilization review, and general program administration. Numerous studies have documented the access problems created for Medicaid beneficiaries by low fee-for-service rates. These problems are compounded for many HMOs who receive even lower payments.

In some states, there is reason to question the appropriateness of paying HMOs at less than 100 % of the fee-for-service equivalent. Two developments may have made the 100 % limit inappropriate. In a few states, the Medicaid HMO program is so large that the Medicaid fee-for-service sector no longer provides a reasonable basis for rate-setting because it is too small and/or unrepresentative. In other states, the state may have been so successful in its Medicaid fee-for-service budget reducing and/or cost-containment initiatives, that it is unreasonable to expect that HMOs can achieve additional short run cost-savings of any significant magnitude. In such circumstances, there may even be reason for paying HMOs 100 % of fee-for-service, and then adding allowances for administrative and marketing expenses which are not built into the rates.

RECOMMENDATIONS

Unfortunately, many HMOs that currently provide care to Medicaid beneficiaries believe that these barriers may eventually decrease HMO participation in the program. Short of restructuring the Medicaid program, GHAA has recommendations for change that may help.

Several of our recommendations deal with expanding certain waiver opportunities to other than federally qualified HMOs. Many HMOs no longer seek federal qualification. Instead, state licensure laws and regulations establish requirements relating to quality assurance, solvency, benefits, access and so on. Although there is, of course, variation among some of the states, efforts by state HMO regulators and insurance commissioners have both toughened requirements and attempted some uniformity by adopting model laws. Similar requirements are in place for HMOs which may be certified as "competitive medical plans" (CMPs) to serve Medicare beneficiaries. Allowing state licensed or CMP eligible HMOs access to these important provisions may expand HMO participation in Medicaid.

To reduce obstacles and encourage HMO participation in the program, GHAA recommends the following:

GUARANTEED ELIGIBILITY: Expand the current 6-month guaranteed eligibility to include state certified HMOs and Medicare eligible competitive medical plans (CMPs).

Currently, Medicaid funding ends with loss of a recipient's eligibility, except that a state may continue benefits ("guarantee eligibility") to beneficiaries in federally qualified HMOs for a 6-month period. Guaranteed eligibility is an important factor--it helps improve the continuity of care, it enhances HMO appeal to the Medicaid eligible, and it stabilizes HMO enrollment. Although likely to be small, additional costs for eligibility guarantees should be funded by Medicaid and not taken from existing HMO capitated rates.

LOCK-IN: Expand the 6-month lock-in to include state certified HMOs and CMPs.

Notwithstanding the enrollees' right to disenroll from the HMO without cause in the second month following enrollment, states may permit a "lock in" of members of federally qualified HMOs (or certain federal grantees) for a 6-month enrollment period. This provision encourages enrollees to consider health plan choices on a basis similar to that of employed populations (where there is normally a year long lock-in), encourages continuity of care and reduces administrative costs.

AUTOMATIC RE-ENROLLMENT/ROLLING ELIGIBILITY GUARANTEE: Automatically re-enroll HMO members who lose and regain Medicaid eligibility within a 3-month period in the program option they had prior to their disenrollment. In addition, eligibility protection should be provided for brief periods (e.g. up to 3 months) of loss of eligibility. There are high rates of disenrollment as a result of loss of Medicaid eligibility. Often this loss of eligibility is caused by errors in eligibility determination, resulting in incorrect disenrollments.

75/25 RULE: Allow an exemption to the 75/25 composition of enrollment rule to include all public HMOs. Consider additional flexibility of this composition requirement to other HMOs in medically underserved areas. Appropriate mechanisms to assure quality and fiscal solvency must be in place.

Under current law, Medicare and Medicaid beneficiaries may compose no more than 75% of an HMO's total enrollment in order to contract with a Medicaid State Agency. Regulations permit a waiver for public HMOs under special circumstances. Because of the geographic distribution of Medicaid populations, a commercial population base of 25% may not be feasible for some providers committed to serving these low-income areas. While the 72/25 rule was intended to insure quality of care to Medicaid beneficiaries, there are better ways of assuring quality care without reducing access to care. GHAA understands the committee's concern as it relates to this provision. However, the waiver provision was put in place because there are special circumstances which should be considered. There must be ongoing oversight to assure that these HMOs and others are in full compliance with appropriate financial solvency and quality standards.

MARKETING IMPROVEMENTS:

States should take action to enhance the caliber of information provided to beneficiaries about the HMO options and make the enrollment process more efficient. Although confidentiality restrictions probably prohibit release of beneficiary names and addresses, states can undertake a limited number of mailings of HMO marketing and enrollment information per year. States can develop mechanisms to allow HMOs access to Medicaid eligibles in welfare offices. Better access and improved communication and coordination also can be developed between HMOs and eligibility or welfare office staff to improve their understanding of the HMO options and thus, their ability to present these options equitably and effectively. All of these changes will reduce the need for individual marketing, particularly on a door-to-door basis in low income areas.

STEPS WHICH CAN MAKE RATES EQUITABLE AND ATTRACTIVE:

- Actuarial Certification: The federal government should require that Medicaid rates paid to HMOs be certified as reasonable by an outside, independent actuary. HMOs look to government to assure that it is a reliable business partner; rates should be based on an actuarially sound, reproducible basis.

- Administrative Cost Allowance: States should provide HMOs with an additional capitation allowance for administrative costs. When Medicaid beneficiaries enroll in HMOs, states are relieved of substantial utilization review and claims processing expenses, which are shifted to HMOs. The HMOs also incur marketing expenses when enrolling Medicaid beneficiaries. These costs are not reflected in the fee-for-service medical cost base.

- Alternative Rate Setting Approaches: Alternatives to fee-for-service based rates should be explored, particularly in areas with high HMO penetration or where the fee-for-service base is inadequate or already subject to extensive cost containment. Rather than paying HMOs a percentage of fee-for-service, it may be more appropriate to pay the equivalent of the full fee-for-service payment level until such time as better alternatives are developed. If alternatives to fee-for-service are developed, they should be actuarially appropriate, with reasonable increases for medical inflation.

- Reporting Requirements: Both federal and state government should take care to establish clear, reasonable reporting requirements for HMOs which are coordinated and consistent with those used by other payors and which are not unrealistically burdensome.HMOs are subject to a variety of regulatory requirements, as well as payor demands. The need to respond to a variety of diverse reporting requirements adds to the HMO's burden and detracts from efficiency. In addition, extensive data requirements unique to any particular payor can serve as a disincentive to participate in the program.

STEPS WHICH CAN SUPPORT STATE MANAGED CARE EFFORTS:

- Information: The federal government should establish a clearinghouse for information on state Medicaid experience with HMOs and managed care, including effective practices and available data. Because of the nature of the federal/state relationship, state experiences are not easily accessible beyond that state. This is inefficient since it requires that each state learn lessons already learned in other states. While each state is unique, there is now sufficient experience that a mechanism for better sharing experiences becomes invaluable. To be maximally effective, this should extend beyond lists of bibliographies or separate reports, to targeted syntheses on an issue or subject specific basis. However, this should not involve new burdensome reporting requirements for HMOs.

- Technical Assistance: The federal government should provide states with technical assistance in rate setting methods and other technical areas which may be beyond the capabilities of many state personnel. States vary in their sophistication and level of understanding of HMOs. Technical assistance can strengthen state efforts and enhance the quality of managed care programs undertaken.

- Freedom of Choice Waivers (2175 Waivers): The federal government should develop alternatives to the present freedom of choice waivers that are less burdensome administratively. One option is to convert these to state plan amendments, with appropriate beneficiary protection provisions. Improvements on the current process will remove some of the disincentives currently facing states considering these initiatives, while reducing the continuing administrative burden on states with ongoing programs.

- State Guidance: The federal government should give better and more effective guidance to states on waiver and other federal requirements. This can improve both the consistency and clarity of federal requirements and objectives, and the efficiency with which states can develop programs to better involve HMOs in the Medicaid program.

ENCOURAGEMENT FOR MORE BROAD REACHING REFORMS: Over time, Medicaid should aim to structure the program such that it resembles--from an enrollment perspective--employment based coverage. That is, beneficiaries should be encouraged to make an affirmative choice among a range of plan options on an annual basis and remain with the plan for a year, as with employed populations. Some consideration also might be given to developing stronger tangible incentives for beneficiaries to enroll in HMOs. This will increase the likelihood that beneficiaries are in a managed care setting and receive coordinated care. It also will reduce HMO administrative expenses and enhance the ability of HMOs to stabilize enrollment and develop appropriate provider contracts and staffing levels.

GHAA believes that it is important to provide Medicaid beneficiaries with access to quality, comprehensive health care services by providing them with the option of enrolling in HMOs. Because of their health care delivery structure, HMOs can improve upon the episodic and uncoordinated method in which many Medicaid beneficiaries frequently receive medical care. Many HMOs have a strong commitment to serving this population. However, some of the problems we have cited make this continuation difficult; not to mention the possibility of attracting new HMO participants. We believe that the recommendations we have just offered are a modest step in the direction of addressing some of these problems and improving the environment to encourage additional HMO involvement in the Medicaid program.

Two additional issues - physician incentives and quality assurance deserve brief discussion as both of these issues were mentioned in the GAO report, which you heard described earlier. Once again we are disappointed in the approach of GAO in their study of HMOs, including recommendations for change which are based on suppositions.

HMO PHYSICIAN INCENTIVE ARRANGEMENTS

HMOs provide care for patients for a preset, fixed payment and incentive arrangements with providers are designed to promote efficient and effective delivery of quality health services. The goal is to preserve quality care and eliminate unnecessary services. HMOs use a complex variety of arrangements to accomplish this and physician incentives are one factor used to affect an appropriate pattern of practice.

An OBRA 1986 provision which prohibits the use of physician incentive compensation arrangements by HMOs, (originally effective April 1, 1989, but extended until April 1, 1991,) was sponsored by Representative Pete Stark (D-CA). This was in response to the "Paracelsus" hospital case where GAO documented financial abuse by a hospital where doctors and the hospital were splitting DRG payments and thus providing a direct financial reward for the inpatient treatment of an individual patient. At that time, Rep. Stark requested a ban on HMO use of physician incentives and asked GAO and HHS to conduct studies. The Physician Payment Review Commission (PPRC) also conducted a review of this issue. Not GAO, PPRC, or the HHS studies were able to show any problems in quality of care linked to the use of physician incentive arrangements by HMOs. We are disturbed that GAO assumes that risk-sharing, which is central to effective managed care, results in poor quality care. GHAA supports continued use of physician incentive arrangements and suggests the following safeguards apply.

Nevertheless, GHAA would like to resolve the issue this year. For that reason, GHAA has developed an approach we believe is appropriate.

The Secretary could not approve a Medicare or Medicaid contract with an organization unless:

- The HMO provides descriptive information satisfactory to the Secretary on the physician incentive plans it employs for services to Medicare and Medicaid beneficiaries;

- The physician incentive plan could not provide specific payments to an individual physician as an inducement to withhold or limit services to individual patients;

- The physician incentive plan could not place physicians at significant financial risk (as determined by the Secretary) for services which are not provided by the physician unless the HMO:

    - provides adequate and appropriate stop-loss protection for the physician, including assurance that the stop-loss protection is appropriate to the size of the patient panel, as determined based upon standards developed by the Secretary (in consultation with the HMO industry and actuaries);

    - and conducts periodic surveys of enrolled beneficiaries to determine, among other things, the degree of satisfaction with access and quality.

QUALITY OF CARE

All HMOs, whether federally qualified, state licensed, contracting with Medicare or Medicaid, must have an internal quality assurance system. GHAA supports strong external review of these systems. Unfortunately, not all such review processes have always been effective or appropriate, but this is changing. For example, the current system of PRO review which reviews "quality" in HMO Medicare contractors, has serious flaws. A description of some of the problems with the current system follows and is relevant in this context because it is the Illinois State PRO which assessed quality in the Chicago HMOs serving Medicaid and this is highlighted by GAO. It also points out some of the problems when quality review standards or approaches applied to HMOs are based on the fee-for-service.

In addition to the HMO internal quality improvement programs, the quality and accessibility of care in HMOs is also assessed through systems of external review. In recent years, external review processes have become increasingly well-defined.

The National Association of Health Maintenance Organization Regulators (NAHMOR), which represents state-level regulators, has just completed a lengthy process of developing model legislation, regulations, and guidelines for quality assurance programs. At present, there is variation in state licensure requirements pertaining to HMOs, but it is anticipated that many states will follow the NAHMOR recommendations. NAHMOR's work, carried out with input from the HMO industry, represents an important initiative to improve state-level external review.

GHAA fully supports the concept of having HCFA work with states to determine and assure that HMOs meet appropriate quality standards. One concern however, is the continued development of multiple layers of quality review, as well as inconsistencies in quality assurance standards and requirements across states and across programs within states. Since all

HMOs are already subject to state licensure requirements, we hope consideration will be given to reinforcing the processes already underway to create more uniformity and appropriate levels of oversight at the state level when fashioning modifications to the state administered Medicaid programs.

PRO REVIEW OF HMOS

One aspect of the Medicare program that has been particularly burdensome for HMOs is the peer review process. The purpose of the PRO program, which applies to both HMOs and fee-for-service providers, is to insure that beneficiaries have access to high quality medical care. It is highly questionable whether this objective is being satisfied, and in the case of HMOs, the program as currently structured may even impede the development of strong internal quality improvement systems.

The origins of the Medicare PRO program rest with the fee-for-service sector. Review of care in HMOs and CMPs was not mandated until 1985. The PRO program was not designed with HMOs in mind--the regulations, quality review approach and organizational arrangements fashioned for the fee-for-service sector were by and large applied to prepaid health care systems.

The current PRO review process is perhaps best described as an "inspection" process: A sample of cases is selected and an "inspector" reviews each one to identify possible problems. If a problem is identified, the provider may be required to develop a corrective action plan and/or sanctions may be levied.

The process focuses on individual cases and individual providers, not systems of care in which there is a defined enrolled population and a defined network of providers and support services.

The PRO process fails to recognize and take advantage of the unique characteristics of health maintenance organizations. For example, cases selected by the PRO for review pertain to beneficiaries who have used medical services or died; the process ignores those beneficiaries that did not "enter" the health system, some of whom may be experiencing difficulties gaining access to needed services. Unlike the fee-for-service sector, HMOs accept responsibility for a defined population of beneficiaries and present a unique opportunity for the PRO to shift its focus from individual cases to population-based quality measures.

Another problem with the current PRO program is that it imposes local fee-for-service standards and practices on the prepaid sector. By Congressional mandate, the PRO program must adhere to the norms and standards that govern medical practice in a community. Since fee-for-service is still the dominant mode of practice in the majority of communities, this mandate results in fee-for-service practices being applied to HMOs. This approach fails to recognize that HMOs are intended to modify medical practice; HMOs are by design expected to place greater emphasis on the provision of comprehensive, coordinated care, on prevention and primary care, and on the elimination of unnecessary services or services of questionable value. Local fee-for-service practice is not and should not be viewed as the "gold standard."

Large HMOs that are national or regional in scope find it particularly difficult to conform to a state-based PRO process. Many of these systems are striving to bring medical practice in line with the best available knowledge regarding efficacy and by doing so to achieve a degree of consistency in medical practice across regions.

Most PROs have failed to establish appropriate mechanisms for representation of HMO physicians within their organizational structures and continue to rely heavily on staff and physician reviewers lacking knowledge and experience in prepaid health care. In light of the fact that there has been some degree of animosity between fee-for-service medicine and prepaid health care in the past, steps should be taken to increase HMO input.

The PRO program's inspection approach to quality review is extremely costly and direct federal expenditures are only a part of the cost. To comply with PRO review, HMOs must increase both professional (R.N.) and clerical staff and incur significant costs associated with the copying and transporting of medical records to a central location for inspection by PRO staff. HCFA does reimburse HMOs for some of the costs of copying (at a rate of $0.05

per page), but needless to say, this falls far short of actual costs. The medical record collection process can also be very complex logistically for HMOs that contract with large numbers of physicians in private practice and with multiple hospitals, home health agencies and other institutional providers.

Benefits derived from the current PRO process are questionable. The process is designed to identify the "bad apples" - not continuously improve the practice of the majority of physicians. Of all the cases reviewed by PROs, only a very small fraction were found to have serious patient care problems. It is difficult to justify continued federal and HMO expenditures in support of a program with such a low yield.

It is time for the PRO program to adopt a new strategy and this strategy should be at least consistent, if not synergistic, with the efforts of managed care organizations to build strong internal quality improvement systems. This is not to say that identifying incompetent or impaired physicians isn't important--HMOs generally do this through their credentialing and recredentialing processes. But there is far greater potential to improve medical practice as a whole by focusing on the typical physician and creating an environment that will encourage marginal improvements in practice. This "environment" is a managed care system that includes information for problem identification, feedback and monitoring; positive incentives for improving performance; strong clinical and managerial leadership; formal and informal peer review processes; and well-defined support systems for providing patient care with appropriate checks and balances.

The PRO program has thus far focused little attention on efforts to promote the development of strong internal quality improvement systems in HMOs. The PRO program does provide HMOs with the option of undergoing a review of their internal quality assurance program, which if found to satisfy certain criteria, results in the HMO being granted "limited" review status. This is a step in the right direction, but unfortunately the "limited review" process has not been structured or implemented properly.

The most serious flaw in the limited review program is the absence of a strong external review process for assessing the adequacy of an HMOs internal quality improvement mechanisms.

Conducting external reviews of internal quality improvement programs is a complex process. Organizations with extensive experience in this area, such as the Joint Commission on the Accreditation of HealthCare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA), have invested a great deal in the development of standards, the training of reviewers, and the specification of a review process. It is not cost-effective nor desirable to have individual PROs develop external review programs. Greater centralization of the external review process is needed. Consideration should also be given to establishing mechanisms to insure that HMOs are not subject to multiple external review programs by the federal government, the state governments, and private purchasers.

In summary, major changes are needed in the PRO program. Some of the problems we have highlighted have application to other programs, such as Medicaid. A process should be put in place immediately to address operational issues such as the need for greater consistency and clarity in PRO practices, mechanisms to facilitate greater input from HMOs at the local level, and problems with the limited review process, to name but a few concerns.

Over the long run, the PRO program and other quality review approaches should experiment with alternative review processes that place greater emphasis on the development of strong internal quality improvement systems and the use of population level indicators of quality rather than the review of large samples of individual cases. It is also apparent that some consideration should be given to centralizing or regionalizing certain aspects of the PRO program, such as the external review process of HMOs' internal quality improvement systems.

The Medicare program is also refining its external review programs. Under consideration is the development of an alternative federal qualification process that would place greater reliance on the development of strong internal systems of quality improvement. This proposal is consistent with the belief that the most effective and efficient method of improving clinical decisions is to incorporate mechanisms for formal and informal peer review into our health care delivery systems.

In addition to federal and state monitoring activities, an independent review organization known as the National Committee For Quality Assurance (NCQA) is actively involved in external review. NCQA is a non-profit organization whose Board of Directors consists of about one-third major purchaser/consumer representatives, one-third HMO representatives, and one-third individuals with expertise in the area of quality. With the assistance of a grant from the Robert Wood Johnson Foundation that was matched by contributions from HMOs and major employers, NCQA is developing an accreditation program for managed care organizations. NCQA's current review activities include a major contract with Prudential Insurance Company to accredit its 42 nationwide managed care operations and special review program involving HMOs in the State of Michigan, the three automobile companies and the United Automobile Workers.

Finally, it is important to remember that the HMO's internal quality assurance system and its use of physician incentives apply to services provided to all the HMO enrollee's. The HMO's goal is to provide appropriate quality cost effective care and in doing so retain members and attract new enrollees.

GHAA looks forward to the opportunity of working with you Mr. Chairman and members of the Subcommittee in making HMOs a viable option in the Medicaid program. We thank you for the opportunity to testify today.

Mr. Towns. Thank you so much for your testimony.

We have been joined by Congresswoman Cardiss Collins from the State of Illinois. I would like to recognize her at this time for any opening statement and any questions.

Mrs. Collins. I have already given an opening statement, and I appreciate you calling upon me at this time. If all of our witnesses have given their presentations, I would like to ask Ms. Shikles:

It was mentioned less than 5 percent of Medicaid patients use HMO's. Is that basically the same facts you found in Illinois when you did the GAO report?

Ms. Shikles. I think in Illinois, about 10 percent of Medicaid recipients participate in HMO's.

Mrs. Collins. That is what I meant. I thought that was a little low for my State—not nationally, but for my State. The reason I thought that was a bit low, I represent a District in Illinois which has a lot of Medicaid beneficiaries, if you will, in my Seventh Congressional District.

Some of the problems we have had in the State of Illinois are problems that have been with the lack of service, and that is one of the reasons why we were anxious some years ago—a couple years ago now, to not only look at the situation in Chicago, but to ask the GAO to do an audit of the service there in the city of Chicago, particularly.

And it came about because many of the Medicaid patients who had been using HMO's were dissatisfied, one, with the service; and second, in the given HMO's, and they found when they were seeking to transfer from one HMO to another, it was usually very difficult.

Did you find that in your GAO audit, that there was some difficulties involved in transferring from one to another?

Ms. Shikles. Yes, we found some of those problems.

Mrs. Collins. Did you say in your recommendations how we could avoid some of those problems?

Ms. Shikles. We focused on a whole set of difficulties and concerns about how the whole program is managed. We wanted much stronger oversight by the State as to all aspects of enrollment and why recipients are leaving. The State never followed up on why they were leaving and how easy it is to get into another HMO.

So, we are concerned about the whole aspect of management of that aspect of the program.

Mrs. Collins. I notice in your GAO report that you mention that there are some disincentives that you found in doing the audit. Could you stipulate some of those for me, particularly when you talked about risk pools and capitation? Could you go into that a little more for me?

Ms. Shikles. We were very concerned. As we mentioned, some of the financial incentives you find in HMO's in your District and other Medicaid-managed care programs, transfer most of the financial risk down to the primary physician level. And then you find that the physician is at risk for not only the services he or she provides, but also specialist referrals and sometimes the physician services portion of hospital services. When you combine this with the fact the physician may be in a very small pool of other providers and cover a small set of enrollees, you set up a real problem for yourself.

For a high cost medical service either the physician will be paying for care out of pocket or there will be underservicing. When you couple the financial incentives with the lack of an adequate quality assurance program to find out what kind of care is being provided, we think you have a very bad situation.

Mrs. Collins. Let me ask you another question. Inasmuch as you have the situation in Chicago—Illinois, I will say where there is very little oversight, if any at all, and you have a number of hospitals that are closing, and a greater reliance in many pockets within densely populated areas of people who want to rely on HMO's or have to rely on HMO's because there is no other available service, and the hospitals are so few they are beginning to go to certain hospitals—Cook County for one, in the city of Chicago—how does that play in providing the kind of quality service that is needed?

Ms. Shikles. Well, I think you touch on a very serious and growing problem, not only in Chicago, but in cities around the country, and we wanted to recommend that HCFA and the different State Medicaid programs combined with public health focus on strengthening HMO's paying physicians to underserve patients, and so, you can take some of the stress off the hospitals.

When people find they can't get the care they need in the communities, they are going to Cook County Hospital and some of the other hospitals, because there is no service available.

Mrs. Collins. Do you believe the problems we have in the State of Illinois with the Illinois Department of Public Aid might be found throughout the Nation, or is it just isolated to the State of Illinois?

Ms. Shikles. No, I agree with your earlier comments. I think what we found in Chicago are problems that relate to HCFA's oversight of the Medicaid-managed care program. We know they have a series of recommendations to expand managed care initiatives in the Medicaid program. We are very concerned these be coupled with very strong oversight mechanisms that will assure quality nationally.

Mrs. Collins. Is HCFA going to be testifying here today? Okay, thank you.

Last year, our Governor in the State of Illinois was asked to sign a bill to increase funding, because I think Ms. Hill, you mentioned about the funding mechanism we have in various States. He was asked to increase the funding in the State Medicaid disproportionate share providers for a year.

This year, he vetoed a very similar bill, so I am wondering what the effect would be, Ms. Shikles, when this veto has been done to the Chicago Medicaid system and related problems that you have already seen in doing your audit.

Ms. Shikles. We are doing several congressional studies looking at the crisis in the emergency room for the uninsured and Medicaid recipients. We are doing studies on crisis in trauma care and other studies relating to access problems for the Medicaid recipient.

We are finding a growing set of problems of uninsured people not having access to care and a certain set of facilities—certain down-town, innercity hospitals—drowning in problems and having difficulty getting enough financing to pay for this care.

Mrs. Collins. Ms. Hill, how did you anticipate we as Members of Congress can do something to protect against the situation where HMO's provide less service to Medicaid patients under a system with a set capitation rate that might be higher or lower?

Ms. Hill. I think the HMO industry as a whole has no objection to tight quality assurance controls. We support them and have developed a number of recommendations of our own of how quality assurance should happen. I can't speak for any of the HMO's in Illinois.

Mrs. Collins. I think you gave some statistics that were national a little bit ago. I think I have referenced to you on more a national basis.

Ms. Hill. I was going to comment, I know in other States, where I am more familiar, there are State health departments that are enforcing very specific controls on quality assurance and doing short audits and all kinds of reviews, and none of the HMO's in those States have any disagreement with those kinds of quality assurance standards.

I think one of the issues that you raise, though, is very important, and that is that as the financial squeeze keeps happening to Medicaid HMO's, those of us committed to providing quality care or no care at all, will have no option but to drop out of the program, because for many of us, it is not satisfactory to provide anything other than quality care.

The Medicaid fee-for-service program pays such a low rate as it is that for HMO's to be expected to do it on 90 percent of the fee-for-service payment, and out of that 90 percent, pay for expenses like going door to door trying to find HMO recipients willing to enroll is an unreasonable expectation.

And so, as I said, those of us committed to quality care will get faced with the choice of having to drop out, and I think that would be truly unfortunate.

Mrs. Collins. Thank you very much. Mr. Chairman, you have been overly generous with your time. I appreciate it.

Mr. Towns. Thank you very much, Mrs. Collins.

Ms. Shikles, are you satisfied that HCFA oversight of Medicaid managed care programs is adequate to insure that enrolled beneficiaries are receiving quality care?

Ms. Shikles. We are not satisfied based on the work we have done looking at Chicago programs of Medicaid recipients.

There were a series of problems going on for several years. HCFA has not made certain that the State has in place an adequate quality assurance program for HMO's, that the kind of utilization data is there to detect if you have a quality of care problem, and that there is a followup program when you discover children are not getting immunizations or other quality problems.

Mr. Towns. Thank you.

Mr. Roslewicz, I have three questions.

You testified that you referred to the findings of your 1989 management advisory report to the FBI for review. Can you tell us what caused you to make the referral and what the status of the FBI review is?

Mr. Roslewicz. Yes, sir.

We decided to refer our finding to the FBI through our Office of Investigations [O&I] within the Inspector General's office. We believe with the appearance of favoritism on a contract involving $633 million and affecting the lives of 87,000 beneficiaries in the city of Philadelphia, we felt this was something that should be referred for investigation.

As far as the status of this goes, I do not know at this time. I would have to go to our office of investigations and supply this for the record.

They are working jointly with the FBI on this case.

[The information follows:]

The FBI opened a case; undertook a limited investigation; and presented their findings to the U.S. Attorney. The U.S. Attorney declined prosecution and the case was closed.

Mr. Towns. At one point in your written statement you indicate that the negotiations between the States and HMA might have resulted in a windfall of about $29.5 million to HMA over the life of the HealthPASS contract.

Did HMA actually receive any of this windfall? If not, how much did the Federal Government contribute?

Mr. Roslewicz. In terms of how much the Government contributed, from the point of time when the contract was awarded by the State, January 1, 1989, to the present time, the Federal funds of $53.5 million have been paid to the State. How much of this applies to the windfall, the scope of audit did not involve monitoring of funds. We were looking at the awarding process.

The instances of the savings we were referring to is that the contract had an agreement in there that the HMA would be paid an amount of—I believe, it was $16.40 per month per individual to the stipulated number of enrollees they agreed to service during the month. That, plus the contract they had for development work, was also going to increase their amount of funds. Our audit work did not include looking into those specific dollar amounts. We can certainly get involved with that.

Mr. Towns. We would appreciate it if you would.

Under current Medicaid law, the Secretary must provide prior approval for contracts between State Medicaid agencies and prepaid plans of more than $100,000. No matching Federal funds are available for services rendered before the date of approval of the contract. The reason for this requirement, which was authored by this subcommittee, was to protect Federal Medicaid funds against contracting irregularities and to be sure that contracting plans have the capital and fiscal integrity necessary to provide quality care to enrolled beneficiaries.

As I understand it, the State entered into a 4 year and 7 month contract with HMA valued at $633 million effective July 1, 1989. On two occasions you recommended that HCFA not approve the contract.

On November 6, 1989, HCFA notified the State agency that the contract with HMA not be approved. At that point, litigation broke out and as a result this contract was amended to terminate this

January 31. A new contract effective January 1 of the next year has been let to the same firm.

Here are my questions.

Has HCFA approved the initial contract between the State and HMA which now terminates on December 31, 1990? If so, when did the approval occur?

Mr. ROSLEWICZ. The preliminary approval came in early December when the court ordered HCFA Regional Office and the State to come to a memorandum of understanding as to what was going to happen with this particular contract. That memorandum of understanding was signed in May of this year. The payments have been made during the whole period of time from July 1, 1989, up to the present time. HCFA checked with the General Counsel to get an opinion as to whether or not they could make those payments based upon the earlier statement that the contract is not really valid if it is not approved by HCFA, which you know it was not.

HCFA said in November they would not approve it. The General Counsel's opinion was that the services were provided to the Medicaid recipients and the Health Care Financing Administration would have to make the payments either under the capitation process or under the fee-for-services process.

So the decision was made. The courts ordered HCFA and the State to come to an understanding, which they did with the memorandum of understanding. That essentially was how the contract was approved.

The contract is scheduled to expire at the end of this year. The new contract is currently with HCFA for review and for approval.

Mr. TOWNS. Have any Federal Medicaid funds been paid out for services rendered before their approval and, if so, how much?

Mr. ROSLEWICZ. To date, $53.5 million was paid by the Health Care Financing Administration to the State of Pennsylvania.

Again, that goes back to the fact that they did receive the General Counsel's opinion that these payments should be paid and the memorandum of understanding approves the contract for this period.

Mr. TOWNS. Thank you.

I think you said your audit focused on procurement rather than program operations.

Mr. ROSLEWICZ. Yes, sir. We were looking at the process which the State of Pennsylvania used to approve and award the contract. We looked at the documentation that was provided by the committees that reviewed the proposals. We looked at the whole process from the time the work was done by the evaluation committees.

There were two. The first went to great detail to document all the steps they had taken. The HMA was rated the lowest on that committee. The second committee was called into place and very quickly went through it and with very little documentation the award was made to HMA.

The scope of our work was to look at the process rather than the effectiveness.

Mr. TOWNS. Did you uncover any instances of wrongdoing? In that process did you find any instances of wrongdoing?

Mr. ROSLEWICZ. What we uncovered was what we thought there might be an appearance of favoritism on the part of the State of

Pennsylvania toward HMA which was the basis on which we referred the matter to the FBI.

We felt that the size of the contract, $633 million, and the number of beneficiaries involved warranted a closer investigation as to what was the motive behind the award.

Mr. Towns. Fine. Thank you.

Ms. Melden, under current law Medicaid beneficiaries may represent no more than 75 percent of the enrollment of a prepaid plan participating in Medicaid. Thus, at least one out of every four enrollees must be a private patient.

Ms. Hill testified that while the 75 to 25 rule was intended to insure quality of care to Medicaid beneficiaries, there are better ways to do so without reducing the access to care. Specifically, an exemption from the 75 to 25 rule and public HMO's have been suggested as alternatives.

In addition, you argue that because of the geographic distribution of the Medicaid population, a commercial population based on 25 percent private enrollment may not be feasible for some provider.

How would you respond to that?

Ms. Melden. I think there has to be a lot of protection put into place to be sure we are not just turning over the capitation rates to what are now Medicaid mills. They are organized. They have figured out how to use these dollars and they are already serving that population.

If the studies are correct that are out there, there are a lot of providers who are already serving the Medicaid program who subsequently went into the capitation programs. This means that it was necessary to use capitation to expand their delivery to that population.

It is not always the case that using managed care will expand access. I think that is what we will have to be aware of when we talk about dropping the 75 to 25 percent requirement.

Mr. Towns. Thank you.

Ms. Hill, I wanted to ask one more question about the physicians' incentive issue.

I understand the need to give physicians financial incentives, but I am concerned when they are so strong, they may compromise decisionmaking with respect to individual patients.

In its testimony, GAO states that six physician groups and two HMO's had assumed the risk for a wide range of primary care services, plus a substantial portion of whose care and speciality services, yet these groups had fewer than 100 Medicaid enrollees over which to spread the risk.

GAO says these groups are not required to prove financial solvency and are not required to enroll private patients. Apparently, HCFA believes these arrangements are appropriate.

Do you believe these physician incentive arrangements are consistent with quality care and do you have comparable arrangements in the plans with which you are associated?

When you recommend to us that the Secretary's review, particularly the physicians' incentive arrangements, determine if they are appropriate, do you contemplate that HCFA will continue to approve the types of arrangements that GAO uncovered in Chicago?

Ms. Hill. With your permission, I would ask Dr. Siegel to answer that question.

Mr. Siegel. Mr. Chairman, the problem and opportunity of incentives for physicians and other health care providers is a complex one.

I think we have today some anecdote practices of a substantive nature that have reflected on the problem of capitation to individual physicians who may or may not have had adequate stop loss protections, an adequate actuarial base in appropriate substantively contractual arrangements to protect their patients.

The GAO supports the declaration requirements of health plans in reporting the relationships of physicians and risk arrangements to the Secretary.

We believe that individual arrangements where physicians may profit by withholding services to individual patients and members are problematic and should be addressed.

We also believe that incentives to groups of physicians with adequate stop loss protections, adequate actuarial basis and contractual basis are entirely appropriate.

We are concerned that the spotlight has focused on the problems of underservice and the incentives through capitation when there is a corresponding and significant problem with incentives for service in the fee-for-service sector.

People are having unnecessary services, having unnecessary surgery, having organs taken away which are still appropriately useful and helpful.

We recognize that provider incentives is a very complex area that has to be addressed in a very constructive manner. GHAA does support a legislative prohibition stating that a physician incentive plan could not provide specific payments to an individual physician as an inducement to withhold or limit services to individual patients.

We also believe that the Secretary in consultation with the managed care HMO industry should set standards for appropriate stop loss protection for physicians participating in HMO's.

Mr. Towns. Are there standards one can apply to these arrangements?

Mr. Siegel. There are many standards. I think first and foremost is the requirement that an HMO have a strong internal quality assurance program, that internal quality assurance program may be validated by external accreditation such as the National Commission for Quality Assurance or other agencies.

We have Federal, State, oftentimes local peer review organizations accrediting the HMO qualifications. It is possible that more specific recommendations within those review agencies may need to be developed. The most important thing is that a managed care program monitor the utilization and qualities of care within it, that it credential qualified providers, that it takes steps to be sure there is no appropriate individual gain to organizations in the form of capitation. This can be addressed in part by having adequate stop loss protections but also more importantly by having appropriate peer review process in place.

Mr. Towns. Thank you very much.

Let me come back to you, Ms. Melden.

Given the problems we are having getting doctors into a lot of low income areas, rural areas as well, should the Government encourage managed care plans in any communities that have those problems, like my district in Brooklyn?

Ms. MELDEN. Well, I think voluntary enrollment is okay. It has to be coupled with a lot more review for quality and with a lot more requirements on the States, that is, external review that they do not underserve.

If it is necessary to expand access, we are not opposed to voluntary programs, voluntary participation in HMO's.

Mr. TOWNS. I guess I should direct this to you, Dr. Hill.

Many sections of my district are medically underserved. In many districts throughout the country you have that problem. Many of my constituents are also Medicaid recipients. Is this the kind of market that is attractive to a commercial HMO or managed care plan?

Ms. HILL. The problem, Mr. Chairman, is that the Medicaid fee-for-service reimbursement rates are very low. Most physicians are reimbursed at a rate for preventative care, which does not cover their costs. So there is no reason for a private practicing physician to open a private office in a neighborhood which is predominately Medicaid recipients. The reimbursements from the Medicaid program don't pay the bills if they participate in a managed care program, and receive their money on capitation, and they work and focus on preventative care, the service savings that are generated by that can be invested in the preventative care and keeping the Medicaid recipient healthy. It is a reallocation of the dollars that are focused on keeping the recipient healthy.

In that situation, a physician taking a fee-for-service reimbursement cannot survive. On the other hand, a community health center that decides to participate because they are in a neighborhood with a lot of Medicaid recipients and, though, cannot make enough on a Medicaid fee-for-service side, they decide to participate in the fee-for-service. They have no motivation for taking patients. The HMO has to be statewide or regional. They are not interested in contracting for their employees with an HMO with one or two offices in an innercity neighborhood inhabited by Medicaid recipients. That is why the 75 to 25 rule becomes prohibitive for getting into the managed care program.

Mr. TOWNS. Thank you very much.

Mr. Nielson.

Mr. NIELSON. Ms. Hill, you are probably the right one to answer this question.

We changed the law in 1981, OBRA which talked about HMO's and said the number of people who could go into the program could increase from 50 to 75 percent.

What if more than 75 percent wanted to go that way? How would you decide which would go?

Ms. HILL. I would suggest an HMO located in underserved areas or public HMO.

Mr. NIELSON. That is not my question. The question is if more than 75 percent wanted it and you are allowed to go to more than 75 percent, how do you decide which individuals take that route?

Ms. Hill. I would not want to see individual HMO's go beyond that and any individual who wanted to enroll would be allowed to.

Mr. Nielson. Mr. Roslewicz, how do you handle that problem? How do you hold it to 75 percent if more want it? How do you decide which ones do not get the opportunity to go?

Mr. Roslewicz. The issue we looked at had nothing to do with the HMO's. We were looking at the HealthPASS contract in the city of Philadelphia.

Mr. Nielson. Maybe I am reading it wrong. It says increase from 50 to 75 percent, the maximum amount of Medicaid beneficiaries that may enroll in a health care plan.

Mr. Siegel. If I may respond, I think we pointed out earlier the tremendous effort it takes to enroll Medicare beneficiaries through an individual recruitment process. It is very cost-intensive. At the same time it would become an effective way of limiting the membership, which would simply stop marketing the plan, close enrollment and solicit no new members.

Mr. Nielson. First come, first served?

Mr. Siegel. Essentially, those already in the plan would stay. Enrollment would not be opened until the 75 percent ceiling was reached.

Mr. Nielson. Ms. Hill, you said the 75 percent ceiling is unrealistic; it should be increased or eliminated?

Ms. Hill. Yes, sir.

Our reason for that is that there are managed care organizations serving Medicaid recipients which are only one or two offices in size. Those offices are located in areas where most residents are Medicaid recipients and there are not many employed people.

Those HMO's don't have the money or ability to market to employers and convince large employers in the area whose employees live all over the region that they should contract with that HMO and send employees there as well. Most employers look for HMO's in the area where their employees live. That is not the need a community service organization usually serves.

Mr. Nielson. Is there any advantage from a financial standpoint to having people switch—we raised it from 50 to 75 percent. Was that to save money or make it more available for more people; if Ms. Hill had her way, move it all the way to 100 percent. I am putting words in her mouth.

Why do we want to increase the number of HMO's and the number of people in Medicaid who go to HMO's?

Ms. Shikles. The administration's position is to increase it so that when you are working in medically underserved areas you can make the HMO accessible to Medicaid recipients.

Our position is that keeping a certain percentage of private patients in the HMO is one quality assurance. When you have a severe concern over the quality of care provided in some HMO's, we would not like to see that relaxed.

Mr. Nielson. You would not want to have it go over 75 percent?

Ms. Shikles. Correct.

Mr. Nielson. Why did you allow it to go from 50 to 75 percent?

Ms. Shikles. I don't think it was done on our recommendation.

Mr. Nielson. So you are saying it is done to provide for the underserved areas.

I want the cost situation. You are in charge of health financing and policy issues. What are the policy implementations of going over 75 percent. Would it cost or save more?

Ms. Shikles. I don't know that there would be a cost implication. I don't think there would be one. We see it as a quality issue.

Mr. Nielson. Would you investigate that, see if there is a financial impact? We know there is a social impact. We know there is a distribution of services impact. We would like to know if there is a distribution of services impact as well.

Ms. Shikles. Yes, sir.

[The information follows:]

The primary purpose of relaxing the patient mix requirement is to encourage more HMO's to participate in the program, particularly in innercity areas where there are few private pay patients. There might be some indirect financial impact if more Medicaid recipients enroll in HMO's. Because HMO payment rates are generally set at 95 percent of comparable fee-for-service costs, increasing the number of Medicaid recipients enrolled in HMO's would, at least theoretically, reduce Medicaid costs. Good data are not available, however, on the cost effectiveness of HMO's.

Mr. Towns. Thank you very much.

Let me thank you for your testimony. Your entire statements will be included in the record.

Thank you very much.

Our next panel addresses a bill of considerable interest to a number of members of this committee, the Medicaid Long-Term Care Services Act of 1989, H.R. 2499. The bill was introduced by Representative Barbara Kennelly, who appeared before this subcommittee on Monday. She addressed a letter I wrote to her last month outlining my concerns about this legislation.

I would like to include in the record a statement of Governor Evan Bayh of Indiana.

[The prepared statement of Mr. Bayh follows:]

Prepared Statement of Governor Evan Bayh of Indiana

Mr. Chairman, thank you for this opportunity to submit written testimony to the Subcommittee on Health and the Environment regarding H.R. 2499 and the Indiana Long-Term Care Insurance Project.

The improved financing of long-term care for the elderly is very important to me and to the citizens of Indiana. With support from the Robert Wood Johnson Foundation, Indiana has designed an approach to this issue that will benefit elderly consumers at no cost to the Federal Government through an innovative combination of high quality private insurance with the Indiana Medicaid program. The Indiana General Assembly passed the State enabling legislation for this program unanimously in 1987. Now we need authority from Congress to move forward and we would appreciate your support.

I hope that you will take a special look at H.R. 2499, the Medicaid Long-Term Care Demonstration Waiver Act, which is under consideration by the subcommittee today. The legislation would allow Indiana and a limited number of other States to conduct public-private long-term care financing demonstration projects. We would like to have the opportunity to test these cost neutral approaches as soon as possible and to collect information that can be useful in evaluating permanent solutions to this critical national issue.

Briefly, the Indiana program will serve the broadest possible range of income groups in the simplest and most equitable manner by providing Medicaid asset protection equal to the amount of insurance benefit payments made for Medicaid-eligible long-term care services to people who are at least 65 years old and who have a medical need or disability. Consumers will have the option of purchasing a qualifying policy at the level of insurance coverage, and asset protection, that they believe they need and can afford. After depleting insurance benefits and becoming eligible for Medicaid, insured individuals will contribute income toward the cost of care in the same manner as other Medicaid-eligible individuals.

By design, the Indiana program's sliding scale approach to asset protection will provide maximum consumer choice and consumer savings, while enabling the State to assure that Medicaid expenditures with the program will not exceed Medicaid expenditures without the program. No one will become eligible for Medicaid sooner than they would have in the absence of the program.

Indiana proposes to prequalify a variety of insurance policies tailored to meet individual consumer needs. The minimum standards for such policies include: (1) compliance with the National Association of Insurance Commission [NAIC] guidelines; (2) coverage of at least nursing home and home care services; (3) optional inflation protection; (4) coverage for at least 12 months and a per diem of $50 per day of care; (5) submission of date regarding the policies in force, use of benefits, effects of underwriting; and (6) other standards developed by a public-private task force.

The State seeks to demonstrate that through this voluntary, incentive-based program it can provide a rational and humane method of financing long-term care, simultaneously improving the quality and affordability of long-term care insurance coverage available to its citizens, reducing financial hardships for the elderly, and offsetting future public expenditures for long-term care. In order to implement the program, the State will need to waive the asset spend-down requirements of the Medicaid program, as provided in H.R. 2499.

I want to thank you, Mr. Chairman and members of the subcommittee, for taking the time to hear testimony regarding H.R. 2499. I hope that you will give favorable consideration to this bill very soon, as it is vitally important to the citizens of Indiana as well as other States.

Mr. TOWNS. James Tallon is the majority leader of the New York State Assembly and a nationally recognized advocate for health care reform. He has worked to assure transitional health care coverage for laid off workers and on proposals on the AIDS education and research.

At the national level, Mr. Tallon also served as chairman of the Committee on Medicaid of the Health Policy Agenda for American people, 172 organizations.

They recommended a range of Medicaid reform including extension of Medicaid to all individuals below the poverty level.

Mr. Tallon is appearing on behalf of the Robert Wood Johnson Foundation to promote long-term care insurance for the elderly. Twenty States have received this. Although it does not have foundation funding, Illinois is also pursuing this issue.

Representative Kennelly's bill would require the Secretaries to grant Medicaid waivers to 10 States to implement these projects.

Mr. Tallon is accompanied by Mildred Shapiro, Associate Committee for Medical Assistance of the State.

Lawrence Thompson is Assistant Comptroller General for the Human Resources Division, General Accounting Office. He is accompanied by Edwin Stropko, Assistant Director, Health Financing and Policy Issues. He will speak on proposals to link long-term care proposals and Medicare, which was prepared at the request of Mr. Roybal of California, chairman of the Select Committee on Aging.

Chairman Roybal has submitted a statement in which he urges the subcommittee to reject H.R. 2499 and cites what he views are the bill's considerable risks to consumers and to the Medicaid program.

Without objection, a copy of Congressman Roybal's statement will be included in the record.

[The prepared statement of Mr. Roybal follows:]

PREPARED STATEMENT OF HON. EDWARD R. ROYBAL, CHAIRMAN, HOUSE SELECT COMMITTEE ON AGING AND ITS SUBCOMMITTEE ON HEALTH AND LONG-TERM CARE

Mr. Chairman and members of the subcommittee, I regret that I cannot be with you today, but I am grateful for the opportunity to share my concerns regarding H.R. 2499, "the Medicaid Long-Term Care Demonstration Waiver Act of 1989," with the members of your distinguished subcommittee.

As you know, in May 1989, the late Chair of the Subcommittee on Health and Long-Term Care, the Honorable Claude Pepper, called upon the General Accounting Office [GAO] to conduct an inquiry into proposed State demonstration projects using private insurance in conjunction with public programs such as Medicaid to finance long-term care costs. Specifically, Chairman Pepper, myself, and the subcommittee sought to have the GAO respond to several concerns. First, the subcommittee wanted to learn whether the proposed projects would result in increased costs to Medicaid. Because long-term care insurance can be expensive—costing over several thousand dollars annually in premiums—persons choosing to participate in the projects may only be those with higher incomes who ordinarily would not be expected to become eligible for Medicaid. Second, we wanted to determine whether the States were adequately prepared to safeguard consumer interests. Previous GAO reports and studies by the subcommittee have found that long-term care insurance is not a good buy at this time and adequate consumer protections are not in place at the State or Federal level.

I am today releasing the report we requested of the GAO. The report, entitled "Proposals to Link Private Insurance and Medicaid Need Close Scrutiny," underscores my view that the current regulatory climate under which private long-term care insurance would be sold is simply not adequate to protect consumers against potentially abusive and deceptive marketing practices. The GAO, who will be testifying later before your subcommittee, note that "long-term care insurance is a relatively new product that is evolving rapidly—more rapidly than State's regulatory and oversight mechanisms." Given recent congressional interest in adopting regulatory reforms to prevent marketing abuses in the sale of Medigap insurance sold to senior citizens, it would be unwise to promote the purchase of a new and more expensive line of insurance, like long-term care insurance, without requiring the States to adopt certain minimum standards designed to protect the consumer. While the GAO agrees that those States participating in the proposed demonstration should be required to adopt certain minimum standards in the long-term insurance area that meet the National Association of Insurance Commissioners [NAIC] standards, we feel that the NAIC Regulatory Standards in this area are extremely deficient. If the long-term care insurance demonstration is approved, minimum standards must go beyond those recommended by the NAIC and: include a prohibition against the use of medical underwriting; require a reasonable minimum loss ratio; mandate a prohibition against prior hospitalization requirements; and protect consumers from unfair pricing practices; and the like. Of serious concern to me is the fact that the General Accounting Office during the conduct of its inquiry into the proposed demonstration, did not have an opportunity to review even one policy that might be sold in any of the States which will be applying for the Medicaid waiver. I do not know how the Congress can wisely legislate this demonstration into existence—a move which the GAO regards as a 'significant policy decision'—without even reviewing the contents of the insurance products the Federal Government would essentially endorse for sale.

Mr. Chairman, of equal concern to me in the discussion of this demonstration program is the fact that it would represent a fundamental change in the philosophy of the Medicaid program. According to current law, the benefits of the Medicaid program become available once an individual's income and assets drop below a certain eligibility threshold. Under the proposed long-term care insurance demonstration, long-term care coverage under Medicaid would kick in once a long-term care policyholder's coverage is exhausted, regardless of the policyholder's remaining income or assets. According to GAO only about 20 percent of the target elderly could even afford to purchase these policies and they are also not the population likely to incur bankruptcy without this protection. To the extent that wealthy Americans are the only ones likely to purchase long-term care protection, Medicaid—the means-tested health program for the poor—would become, under this demonstration, an asset protection program for the rich. Obviously, this was not the intent of the Medicaid program when created and not should it be so today.

Let us acknowledge that we are not just talking about a 10 year demonstration project. GAO makes that point as well, staging "while the projects are considered demonstrations, their commitments to project participants may require that they operate for 20 years or more . . . consequently, authorizing the demonstrations would represent a significant policy decision." Given the demonstration's long operating timeframe, its lack of a regulatory framework to protect consumers, its susceptibility to deceptive and abusive marketing practices, its limited scope of beneficiaries and its potential for increased costs to the Medicaid program, I believe it would be a grave and disastrous move for the Congress to authorize this demonstration. It is not an answer to our long-term health care problems. Sadly, if this demonstration were enacted it might possibly give millions of Americans of all ages—who become bankrupt annually due to the high costs of their chronic illness—a false sense of security.

I commit the GAO report to you for further review and commend you on your careful consideration of this important matter.

Thank you.

Mr. Towns. Phyllis Torda is Director of Health Policy Families U.S.A., an organization which focuses on the health of low income elderly.

Earlier this year, the foundation issued two reports, one on the affordability of private long-term care insurance and one on the industry's treatment of frail elderly purchaser. Her testimony this morning applies the lessons learned to the bill before us.

Without objection, all of your written statements will be included in the record in full.

I would like to ask each of you to please limit your initial remarks to under 5 minutes. May I begin with my colleague from the great State of New York, Mr. Tallon.

Senator Tallon.

STATEMENTS OF JAMES R. TALLON, JR., MAJORITY LEADER, NEW YORK STATE ASSEMBLY, ON BEHALF OF THE ROBERT WOOD JOHNSON FOUNDATION, ACCOMPANIED BY MILDRED SHAPIRO, COMMISSIONER, ASSOCIATE COMMITTEE FOR MEDICAL ASSISTANCE; PHYLLIS TORDA, DIRECTOR, HEALTH POLICY, FAMILIES USA FOUNDATION; AND LAWRENCE H. THOMPSON, ASSISTANT COMPTROLLER GENERAL, HUMAN RESOURCES DIVISION, GENERAL ACCOUNTING OFFICE

Mr. Tallon. Thank you very much.

I am pleased to be able to address the subcommittee on behalf of the program to promote long term care insurance for the elderly. The purpose of the program is to test models of public-private partnership for the financing of long-term care.

As you know, New York is one of the States involved in planning and implementation of these demonstration programs. As chairman of the health committee, and majority leader of the Assembly, I have been directly involved in promoting New York's involvement in this innovative project.

I have cosponsored the State authorizing legislation (chapter 454, 1989) which passed both Houses unanimously, which authorizes our participation.

I will focus my remarks today on Medicaid generally, the urgent need for innovation in the area of long-term care financing, and why New York committed itself to the partnership strategy included in the demonstration proposal.

Additional written statements will be submitted for the record to provide a more detailed description of the overall approach and each State's proposed models. In addition, the national program director and each State project director are available to subcommittee members and staff for future questions and discussion.

Mr. Chairman, although we work in different venues, we share many common interests and concerns relating to improvements in the health care system. In Washington and in Albany, we have found the legislative and fiscal battles to protect and enhance the Medicaid program.

Medicaid has overcome many challenges to become an essential part of America's social safety net. Yet we acknowledge its imperfections, and each year work to incrementally improve the system.

We also share a strong commitment to promoting broader health care reforms, measures which would build a comprehensive system of access and protection for all. Some confidence can be gained from the public opinion polls which show increasing support for a national system of health care financing, and we know that it will take more time to achieve that goal.

But Medicaid is in serious trouble now. Our success in expanding the program for certain groups is offset by fiscal attrition, if not overt cuts, in other areas.

Further incremental steps will be necessary to assure that Medicaid continues to protect those who have alternatives for health care access, those who our predecessors agreed to serve when they established Medicaid in 1965.

As the Federal and State levels of Government face increased demands and constrained resources, we will have to increase our efforts to protect and improve Medicaid in the immediate future, regardless of the design and timetable for national reform.

The fundamental challenge facing Medicaid today is our collective ability—in Congress and State legislatures—to generate the resources necessary to serve current and future Medicaid recipients. We are forced, particularly at the State level, to make our Medicaid investment work more effectively and efficiently. And, we have introduced greater flexibility into important areas of Medicaid policy and administration, gradually discarding elements which we deem too restrictive, or irrelevant to the contemporary demands placed on the program.

It is within this context that my colleagues in other participating States and I have come to support the proposed long-term care insurance demonstration. I will briefly highlight what I view as the critical strengths of this proposal.

First, many of the elderly who are now Medicaid eligible were not poor when they first entered a nursing home or began receiving intensive home care services. Instead, they expend the bulk of their income and assets to pay for these services, or they find ways to shelter their resources, and eventually they become eligible for Medicaid. This situation is all too common due to the lack of financing alternatives. The demonstrations will provide an alternative to impoverishment, and promote awareness about the need to plan for future long-term care needs.

Second, alternative means of financing long-term care are essential to preserving Medicaid's viability for those who are truly poor. Medicaid was not intended to be the financing mechanism for the majority of elders' long-term care needs. There is an identifiable population of higher income elderly now receiving Medicaid who must be induced to try alternative private financing models.

Finally, our demonstration programs are designed to test whether private long-term care insurance coupled with revised Medicaid eligibility requirements provides an effective structure of incentives to reform the long-term care financing system. Demonstration of this approach should provide the following benefits: invaluable experience upon which to base future, national long-term care reform; improved insurance products which are coordinated with State long-term care services; and a more rational and humane method of financial protection for long-term care expenses.

The States participating in this demonstration program seek the opportunity to test the potential—and the limits—of private long-term care insurance. However, we also want to determine if this model would be effective in containing Medicaid costs.

The proposed Federal bill would require each State to demonstrate cost neutrality on a per capita and aggregate basis. In New York, our estimates indicate a substantial savings under this demonstration despite the proposed eligibility revisions.

This is a refreshing contrast to other Medicaid cost containment schemes. We do not propose reducing eligibility or benefits for those currently Medicaid eligible. We do not propose eliminating optional Medicaid features. We do not propose to shift more uncompensated costs onto providers. In fact, those who are now served under Medicaid at States' discretion will indirectly benefit to the extent that long-term care cost growth can be effectively controlled under one or more of the demonstration models.

These projects will also provide a rich source of data and experience which could be vital to future policy discussions on long-term care. Our current knowledge about utilization and expenditures is primitive at best; this is particularly troubling given the level of current public investment involved.

We have identified a legitimate method of controlling public sector health care costs, while protecting seniors' income and assets and offering meaningful coverage for long-term care expenses.

Given the above points, and the need to begin the process of planning for future funding of long-term care, I believe our request for the necessary Federal waiver authority has substantial merit.

In many respects why the program is less able to deal with the needs with a population of nonelderly poor for whom you and I have expressed great interest over the years—at the State levels we need an alternative. We need to be able to take another alternative to approach this project.

In conclusion, I have asked myself if I am philosophically abandoning people in the Medicaid program. I believe not. I believe we are allowing people who are subjected to a process of impoverishment to share among them the risk. Pooling that risk, I don't think philosophically alters the basic structure of that program.

Thank you.

[The law referred to and additional material follow:]

(Chapter 454, Laws of 1989)

Long term care security demonstration program for long term care

1. The commissioner, in consultation with the commissioner of health, the superintendent of insurance and the director of the state office for the aging and subject to the approval of the director of the budget, is authorized to establish a long term care security demonstration program for long term care. The commissioner may establish income and resources tests for eligibility for benefits under the program.

2. The commissioner shall apply for any necessary waivers pursuant to subdivision (2) of section 1915 of the federal social security act necessary to implement this section. Utilization of medical assistance funds to pay for care and services to persons pursuant to this section shall be provided so long as federal financial participation is available for such care and services.

3. Notwithstanding any inconsistent provision of law, the long term care security demonstration program established pursuant to subdivision one of this section may provide that a person whose income and resources exceed the limits provided in subdivision two of section three hundred sixty-six of this title may be eligible for long term care services under the medical assistance program in accordance with this subdivision if such person: (i) is covered by an insurance plan providing long term care services which meets the minimum benefit standards established pursuant to section three thousand two hundred twenty-nine of the insurance law and which is approved by the superintendent of insurance, in consultation with the commissioners of health and social services and the director of the state office for the aging, and (ii) has exhausted all coverage and benefits provided by such plan provided, however, that the commissioner may provide for assistance with deductibles prior to exhaustion of all coverage and benefits provided under such plan for persons eligible under this section. For the purposes of this section, long term care services shall include, but not be limited to, care, treatment, maintenance, and services provided in a residential health care facility qualified as a provider in the medicare program pursuant to title XVIII of the federal social security act or provided by a home care services agency, certified home health agency or long term home health care program, as defined in section thirty-six hundred two of the public health law or a personal care provider licensed or regulated by any other state or local agency. Provided further, however, the state shall not utilize any medical assistance funds to pay for any insurance plans providing long term care services to eligible persons pursuant to this section written five years after the effective date of this section. Medical assistance funds shall continue to be available for any existing insurance plans providing long term care services to eligible persons pursuant to this section regardless of whether the provisions of such section remain in effect.

4. Notwithstanding any inconsistent provision of law, rates of payment under the medical assistance program for long term care services after the exhaustion of all coverage and benefits provided by an insurance plan described in subdivision two of this section shall be reduced in accordance with regulations of the department, promulgated in consultation with the commissioner of health and the director of the state office for the aging, by an amount which the provider of such long term care services may charge the eligible individual.

5. No demonstration program authorized by this section shall be undertaken unless the commissioner reasonably estimates that the aggregate state expenditures under the program would be less than without the program and the director of the budget approves such program.

6. The department shall submit an annual report no later than January first of each year beginning January first, nineteen hundred ninety-one. Such report shall include a description and the number of policies issued and an analysis of the cost effectiveness of the program authorized pursuant to this section.

(Added L.1989, c. 454, § 1.)

Historical Note

Effective Date. Section effective Nov. 13, 1989, pursuant to L.1989, c. 454, § 3.

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PRIVATE VS. SOCIAL LTC INSURANCE

BEWARE THE COMPARISON

by MARK R. MEINERS & HUNTER L. McKAY

The debate about whether social or private insurance is the best way to solve the nation's long-term-care financing problem is a positive step in our thinking. The debate signals the acceptance of insurance principles as the basis for long-term-care reforms. However, a major myth seems to underlie the comparison between social and private insurance. The myth is that social insurance and private insurance are competing strategies for solving this country's long-term-care financing problems. This type of thinking can be used to set an argument in which social insurance looks appealing and private insurance looks inadequate. If accepted by the public without closer scrutiny, this comparison could easily raise expectations about social insurance strategies that cannot be met and could thus be damaging to progress and lasting success.

A more constructive point of view is that private insurance can be an important piece of the long-term-care financing puzzle that needs to be integrated with current public programs, most notably with an improved Medicaid program. In this article we suggest that the implications of repealing the Medicare Catastrophic Coverage Act of 1988, the fact of competing priorities, and the role of public preferences are important considerations that support this integrated approach. The development of private market insurance options provides a basis upon which to build needed improvements in our current long-term-care financing system.

PRIVATE VS. SOCIAL INSURANCE

No one who has seriously studied the issue of long-term care sees the development of private market insurance options as a panacea for our long-term-care financing problems. Private insurance participation is voluntary and depends on the market appeal of a given benefit package and on the consumer's insurability and ability to pay the premium. In contrast, social insurance strategies generally make participation mandatory, covering everyone (or all those in selected groups such as the elderly and the disabled), mandate the level of coverage for selected services, and spread the financial burden through taxes on the general population.

The myth is that social insurance and private insurance are competing strategies for solving this country's long-term-care financing problems.

Almost by definition then, social insurance proposals can be more comprehensive both in who the insurance covers and how it covers them. The major limiting factors (besides possibly not being responsive to individual preferences) are the cost of social insurance strategies and the public's tolerance of taxes to pay for them. During the most recent period of legislative interest, numerous long-term-care proposals were introduced on Capitol Hill with price tags ranging from $5 billion to $55 billion. New proposals to generate the necessary revenues include raising or eliminating the cap on the Medicare payroll tax, a surcharge tax on gifts and estates over a certain amount, increasing alcohol and cigarette taxes, and a new income tax surcharge.

The tax-tolerance factor is not insignificant in the debate. While some of the proposed taxes may seem plausible as logical revenue sources for long-term-care needs, Congress is faced with a myriad of programs and constituencies, all of which could benefit from those same revenues, whatever the specific tax vehicle used to generate them. Very recent history provides ample evidence of pitfalls in tax strategies used in trying to add catastrophic protection to Medicare, our country's only social health-insurance program. The need for social insurance is not clearly and uniformly perceived, even by the very constituencies of the senior citizen organizations that promote these proposals.

Once we begin to factor in the cost of insurance programs that feature comprehensive benefits, minimal premiums, and no means test, numerous compromises are introduced. The recent wave of legislative proposals on long-term care made ample use of cost-sharing techniques including co-payments, deductibles, and premiums in addition to major new taxes in order to raise the necessary revenues. These proposals reveal that to be economically feasible, social insurance programs may have to resort to many of the same cost-containment strategies used by private insurers.

This situation tends to "even the playing field" on which social insurance and private insurance can be compared and provides a basis for understanding the significant cost implications associated with social insurance strategies. It also reinforces the fiscal reality that the most likely solution to our long-term-care financing problems will take the form of a public-private partnership. A realistic approach to achieving this end is to encourage the private market to be an appealing and effective partner in long-term-care financing by structuring linkages between private insurance options and access to an improved Medicaid system (Merrill and Somers, 1989).

IMPLICATIONS OF MEDICARE CATASTROPHIC

Though many of the social insurance proposals involve expansions of the Medicare program, the recent experience with adding benefits to Medicare suggests that mounting a new national program can be fraught with difficulties. Some say that the reason elders reacted negatively to the Medicare Catastrophic Coverage Act of 1988 was a misplaced focus; long-term care, they say, is what people really want, and people would be willing to pay for it. Basic to this view is the notion that long-term care is a family issue, affecting everyone. Others contend that Congress will be very hesitant to move forward on any new national health initiative for the elderly, particularly given the perception that the elderly are not willing to pay the costs. There is also the feeling that increasing the tax burden on the general population for programs primarily geared toward the elderly will not be acceptable at this time.

Adjustments to the Medicaid program may be a more feasible approach to improving our long-term-care system. Congress has shown favor to this idea, even as it has moved away from support for Medicare catastrophic benefits. The Medicaid-related provision that would protect from impoverishment those persons with spouses in nursing homes is one of the three benefit enhancements in the Catastrophic Coverage Act that were retained.

Table 1

IMPORTANT SOCIAL ISSUES
AS RATED BY ADULTS IN THE U.S.

Issue	*Percent Who Rated It Extremely Important*
Strengthening the campaign against illegal drugs	57.3
Improving the quality of public education	56.9
Maintaining Social Security benefits for senior citizens	46.9
Cleaning up the environment	46.6
Long-term care for elderly and disabled	46.6
Control and cure of the AIDS epidemic	41.4
Providing training and jobs for the unemployed	39.2
Ensuring a strong national defense	33.2
Providing food and shelter for the homeless	28.0
Affordable housing for all Americans	27.2
Providing health insurance for uninsured people	24.0
Giving economic aid to poor countries	7.1

Note: Issues rated did not include the federal budget deficit.

COMPETING PRIORITIES

Before the controversy over the Catastrophic Coverage Act, speculation had centered on whether there would be much congressional interest in new national healthcare initiatives. Many issues needed attention, and it was not clear whether long-term care or healthcare for the uninsured, the two other key contributors to catastrophic healthcare costs, would take precedence in any healthcare reform efforts that did emerge. Congress assigned both these issues to the Pepper Commission and asked for recommendations on how to proceed.

Results from a survey of the adult population, conducted around the time of the presidential election, provide a sense of the public's attitudes on these and other competing priorities (Meiners, 1989). In the context of current fiscal constraints, the survey found that the American public viewed long-term care for the aged and disabled as an important problem, though not the top priority (see Table 1). Issues such as use of illegal drugs, quality public education, cleaning up the environment, and maintaining Social Security benefits were viewed as more important. Of the two issues under consideration by the Pepper Commission, long-term care was clearly viewed as more important than health insurance for the uninsured.

How makers of public policy interpret these results is not necessarily clear. While there is no question that long-term care is a major issue that needs to be addressed, the issue of competing priorities is important in that social insurance proposals seek additional tax revenues for assisting elders rather than other groups with less ability to assist themselves.

The uninsured provide an example of one such group. In contrast to long-term care for the elderly, Medicaid benefits are not generally available to those of working age who are unable to afford insurance, and there is no analog to Medicare to cover acute-care needs.

PUBLIC PREFERENCES

The survey also sought to determine the public's view of long-term-care needs and financing, including attitudes toward private long-term-care insurance. The final series of questions asked about the government's role in paying for this care. First, the survey presented the idea of government helping people to buy long-term-care insurance. Almost three-quarters of the respondents were in favor of this idea.

Next the idea of cost sharing for a new long-term-care program was introduced. The first option presented was a partnership in which individuals paid two-thirds and government paid one-third of costs. Two-thirds of those surveyed responded favorably to this kind of split in the financial responsibility. While their willingness to directly assume this level of the financial responsibility seemed surprising, the response was consistent with the findings of the final set of questions.

Respondents were asked if they favor government programs, funded with tax dollars, that cover everybody regardless of income, or programs that help only the most needy. Programs focused on helping the most needy were preferred by 60 percent of the respondents. Thirty-five percent preferred a government program for all, but about a quarter of this group were not willing to pay their share of the new taxes that were estimated as necessary to cover the cost.

Taken together, the survey results suggest that the public recognizes that practical and equitable solutions will involve both the public and private sectors. The public is receptive to the idea of private long-term-care insurance to help in this regard if the products will provide the protection consumers feel they need. Support also exists for cost sharing with the government, which may help to achieve a broader market. The most preferred role of government is to focus assistance on the most needy. This attitude appears to be grounded in recognition of the limits imposed by the federal budget deficit as well as resistance to the idea that a total government solution is the best way to proceed.

PUBLIC-PRIVATE LINKAGES

The survey findings illustrate what we contend is the real reason that the debate about social insurance versus private insurance is such a major step forward: Long-term-care financing has operated over the years through a rough linkage of public and private responsibility. Much of what is needed in caring for people with chronic illness has been provided as part of the informal process of dealing with aging, with substantial amounts of care (commonly estimated to be as high as 80 percent) provided by family and friends. In addition, individuals and their families pay nearly half the cost of nursing home care out-of-pocket, with the other half covered by the Medicaid program but only after an individual has become impoverished. The development of long-term-care insurance options began to be recognized in the early part of this decade as a better approach to the public-private "partnership" that could also help relieve some of the pressure on the Medicaid system (Meiners, 1983).

Clearly there is already a significant sharing of the responsibility, but it is not satisfying to either the individual or the government. Without an opportunity to pool risk, long-term-care recipients and their families must pay out-of-pocket until they become impoverished. Medicaid, a program designed to pay the healthcare bills for the poor, has become known as the payment source for middle- and upper-income elderly by way of the "spend-down" process and in some cases by resource transfers.

Adjustments to the Medicaid program may be a more feasible approach to improving our long-term-care system.

In effect, people who need long-term care are faced with a deductible equal to most of their assets and copayments equal to most of their income if Medicaid is to be their long-term-care insurance program. This "all or nothing" approach to insurance from the public side has had troubling implications for both consumers (primarily the elderly) and public payers for many years. However, the very fact that there is an existing public program like Medicaid that is available to the elderly who cannot pay their medical bills provides an important foundation from which to work toward social insurance goals. This is especially true if one recognizes that a market for private insurance can provide consumers with better opportunities for covering their share of the bill, which could also help relieve some of the pressure on the Medicaid system.

The rapid emergence during the past few years of private market long-term-care insurance options has served to sharpen the debate as to the relative roles of the private and public sectors in paying for long-term care. By explicitly involving Medicaid as a base, private insurance can become part of an improved financing system in which the burden of long-term-care costs is shared in a way that ensures that elderly people will have the opportunity to receive needed care during their declining years without having to impoverish themselves.

A PARTNERSHIP PROGRAM

In spite of rapid growth in recent years, the market for long-term-care insurance is still small and emerging. Many products are too expensive for the general population and have been the subject of criticism concerning features and limitations. One program that is seeking to address these concerns as well as those associated with the uncertainty about how best to proceed with new national strategies is the Robert Wood Johnson Foundation Program to Promote Long-Term Care Insurance for the Elderly, currently under development in eight states.

The states—Connecticut, Massachusetts, Indiana, Wisconsin, New York, New Jersey, California, and Oregon—with grant and technical assistance support from the foundation, are designing cooperative public-private partnerships in long-term-care insurance. The intent of this program is to build on the significant responsibilities and experience that states have in the financing and delivery of long-term care. The states are seeking to address the challenge of coordinating the role of the private sector with current and emerging public programs. While long-term-care systems differ across the states, the need for financing reform is common.

The goals of the program are outlined in the box below. To accomplish these goals, each state is developing an operational partnership and corresponding demonstration project covering nursing home and community-based services with a coordinated case management component for service delivery (Meiners and McKay, 1989). Various strategies are being considered to encourage the purchase of private insurance options by those who can afford them, assisting those who can only partially afford them, and assuring coordination with programs that are fully publicly funded. Among the interventions being explored by the states are the following:

- Educational campaigns to increase awareness among elders about their lack of protection and their purchase options.
- Increased consumer protection through better regulatory oversight.
- Coordination of public and private program components to encourage efficient use of resources and to provide a smooth transition from private to public resources.
- Medicaid eligibility standards that recognize the costs paid by private insurance plans.
- Reinsurance pools to lower the premiums for all purchasers and subsidy plans that make premiums affordable for low-income elders.
- Special offerings to state employees and group approaches that utilize lower administrative costs to make insurance more affordable.

The timetable for completion of the planning phase varies in each state. The state of Connecticut has already applied to the Robert Wood Johnson Foundation and has been approved for demonstration funding. A review of the Connecticut program, which highlights the merits of the basic approach being developed to create linkages with Medicaid, is provided elsewhere in this issue (see Mahoney, page 71). The planning grants should be fully completed for all states by the fall of 1990. In addition to seeking demonstration funding, states are also engaged in working with their legislative liaisons to seek federal waiver authority, which will allow the Secretary of Health and Human Services to waive certain aspects of federal Medicaid regulations.

SUMMARY DISCUSSION

Makers of public policy should be cautious when they are presented with choices that pit social insurance against private insurance as competing options for accomplishing long-term-care financing reforms. To be sure, the current offerings of private products are subject to improvement, and private insurance alone cannot accomplish social insurance goals. However, private insurance explicitly tied to improvements in Medicaid could serve to move us toward an improved national long-term-care system.

The fiscal strain of competing priorities as well as public resistance to new self-financing programs suggest that this type of strategy must be seriously considered. Incremental strategies that encourage as much personal responsibility as possible are necessary for progress to be made. The existence of a government program like Medicaid as a backup makes the financing structure of long-term care unique.

Building on Medicaid, a state-centered approach allows for the development of financing reforms that are consistent with the reality of present economic and political conditions. The partnership program contains incentives for maintaining informal supports and allows elders some voice in determining what kind of insurance they would prefer and how much they would like to pay for it. The emergence of private insurance options that work in partnership with state Medicaid programs can be viewed as complementary to the implementation of the details of most social insurance proposals. The experience of states in creating and administering partnership financing programs could provide the basis for further reform of the current system or for the creation of a national insurance program. ■

GOALS

ROBERT WOOD JOHNSON FOUNDATION PROGRAM TO PROMOTE LONG-TERM CARE INSURANCE FOR THE ELDERLY

- Assist elders to avoid the impoverishment required by Medicaid for those using long-term care.
- Promote greater access to insurance protection by working with insurers to develop products which are affordable by a large segment of the elderly population.
- Encourage development of coordinated long-term-care delivery systems that combine both private and public funding sources.
- Allow elders to plan for their long-term-care needs in a manner that maximizes personal choice.
- Encourage development of a unified long-term-care system in which all elders are treated equally.
- Conserve public resources for those truly in need by alleviating middle-class elders' reliance on Medicaid.
- Remove the incentives for elders to transfer assets or otherwise "game" the system to gain Medicaid eligibility.

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Mr. Towns. Thank you.
Ms. Torda.

STATEMENT OF PHYLLIS TORDA

Ms. Torda. Mr. Chairman, I am Phillis Torda, director of health policy, Families USA Foundation.

We have two concerns here. First, the approach is not likely to benefit very many individuals, low income Medicaid beneficiaries could be disadvantaged by this approach.

Private long-term care insurance is unaffordable for a large majority of seniors. The Families USA Foundation study shows that 85 percent of older Americans cannot afford private long-term care insurance premiums.

The other major problem with private long-term care insurance is underwriting. Companies refuse to issue policies to individuals with situations that increase the risk. In addition, the individuals refuse to pay claims, even though they have been collecting premiums from the individuals.

The partner States hoped linking insurance to Medicaid profitability would be able to allow the insurers to lower premiums. Only one response to Massachusetts' request for proposals always included premiums. Those premiums are significantly higher than Massachusetts expected.

Those insurers who submitted proposals to Massachusetts expressed serious reservations about covering everyone who applies. The insurers pointed out that the group who applies for insurance will be less affluent and in poorer health than the general population as a whole.

It is questionable that the partnerships will protect significant numbers of individuals from exhausting their assets in qualifying for Medicaid. States entering into partnerships should establish higher standards for private insurance policies.

The proposed legislation could disadvantage low income Medicaid beneficiaries in several ways. The private-public partnerships could cost States money rather than save money; and public-private partnership participants could receive more favorable treatment from the Medicaid program than other Medicaid beneficiaries.

Public-private partnership participants could have higher incomes; be allowed to keep more money for personal needs; and could displace other Medicaid beneficiaries as they compete for nursing home beds.

The Federal Government must scrutinize State estimates of savings to be sure they are based on reasonable assumptions. If States are allowed to spend Medicaid funds on these projects in any one year there is a risk that promised savings will not materialize in the future.

Approximately 19 percent of all seniors have incomes just above eligibility. Higher pressure marketing tactics could easily convince seniors to buy policies at great financial sacrifice. It would be tragic for low and moderate income seniors to scrape together limited dollars to participate when there is a strong likelihood that they will qualify for Medicaid by the time they will qualify for long-term care.

New York State found a higher percentage qualified before they entered a nursing home. At least one State is asking to waive Medicare requirements for purchased and approved policies. There are good reasons to allow seniors needing long-term care to protect some of their assets, but there is no reason why seniors with enough income to pay for long-term care out of pocket should ever be eligible to receive assistance through the Medicaid program.

This legislation would allow demonstrations affecting potentially one-third of our Nation's seniors. The Federal Government would insure a permanent obligation to provide permanent long-term care benefits to all individual participants. There may be a couple of States in which it makes sense to experiment with private-public partnerships under specific terms.

The Federal Government should evaluate individual States' proposed public-private partnerships and approving the few that offer the most potential, given the characteristics of the Medicaid program in those States.

Under no circumstances should waivers be approved without strict and specific standards for the qualifying private insurance. Neither should any waiver allow public-private partnership participants to be treated more generously than other Medicaid long-term care beneficiaries, except for treatment of assets.

Thank you.

[Testimony resumes on p. 512.]

[The prepared statement of Ms. Torda follows:]

Testimony by

Phyllis Torda
Director of Health Policy

Families USA Foundation

Mr. Chairman, I am Phyllis Torda, Director of Health Policy for Families United for Senior Action (Families USA) Foundation. I am pleased to have the opportunity this morning to provide the subcommittee with our views on the Medicaid Long-term Care Demonstration Waiver Act of 1989, H.R. 2499.

This legislation would give the Secretary of Health and Human Services authority to waive virtually all requirements of the Medicaid program necessary to implement public/private approaches to long term care financing in up to ten states. Connecticut Governor O'Neill has asserted, in a New York Times op-ed, that this approach is the answer to our nation's long term care problem. Families USA disagrees.

Families USA has serious concerns about the proposed public/private partnership approach to providing protection for long term care. Our concerns fall into two broad categories: First, this approach is not likely to benefit very many individuals; and second, low income Medicaid beneficiaries could be disadvantaged by this approach which would grant Medicaid eligibility to more affluent individuals.

AFFORDABILITY AND COVERAGE LIMITATIONS

Research by Families USA and others has demonstrated two significant problems with private long term care insurance. The first major problem with private long term care insurance is that it is unaffordable for a large majority of seniors.

The cost of basic long term care policies from nine leading companies averages $1,255 annually for those purchased at age 65 and increases to $1,808 for those purchased at age 70, and to $2,879 for those purchased at age 75. Families USA Foundation's study, **The Unaffordability of Nursing Home Insurance**, showed that 84 percent of older Americans could not afford those premiums. Two-thirds of older Americans could not afford even the lowest priced basic nursing home policy.

To determine affordability, our study used a standard more conservative than that used by the Reagan Administration to define a catastrophic health cost. The Reagan Administration defined health care costs in excess of 10 percent of a person's income as "catastrophic." Our standard looked at whether these costs exceeded 10 percent of the value of individuals' annuitized assets, as well as their income.

The second major problem with private long term care insurance is that insurance companies are not providing coverage for many who need it most. This happens because of insurance underwriting -- companies refuse to issue policies to individuals with health conditions that increase their risk of needing long term care. In addition, insurance companies have refused to pay claims even though they have been collecting premiums from the individual.

Families USA Foundation's second report, a preliminary report on insurance industry abuse of frail elders illustrated the many problems purchasers of long term care insurance have collecting their benefits. Long term care insurance is a high stakes enterprise. Annual premiums for the elderly begin at about $600 and can exceed $4,000. Claims of one policyholder can easily amount to over $100,000. The amount of premium and claims dollars at stake provide incentives for agents to make quick sales, then for companies to subsequently deny claims.

Our report also described cases where insurance companies arbitrarily determined that they would cover only a lower, cheaper level of care, despite substantial medical evidence that a higher level of care was warranted.

THEORY AND REALITY

The proposed public/private partnerships are not likely to produce private insurance premiums that are affordable for a substantial number of seniors. Neither are the partnerships likely to produce underwriting practices that result in private insurance coverage for many seniors likely to need long term care. In fact, Congresswoman Kennelly testified against any prohibition of medical underwriting.

The public/private partnership approach to financing long term care has been promoted by the Robert Wood Johnson

Foundation. In 1988 the Foundation developed premiums used to model the results of the public/private partnerships. In 1990 dollars, these premiums range from $460 for a one-year policy at age 65 to $2,601 for a three-year policy at age 80. Such premiums are significantly below the average 1990 premiums cited above for basic policies currently being marketed.

Public/private partnership states have hoped that linking purchase of private insurance to Medicaid eligibility would produce a marketing advantage that would enable insurers to lower their premiums. Only one response to the Commonwealth of Massachusetts's request for proposals included premiums. That insurer, American Express, proposed premiums ranging from $705 for one year of coverage purchased at age 65 to $3,812 for lifetime coverage purchased at age 69. Again, these premiums are significantly higher than the premiums used by the Robert Wood Johnson Foundation to model the results of the public/private partnership approach.

It does not appear that the public/private partnership proposals will induce the insurance companies to offer more affordable premiums. The projects, therefore, will not be able to accomplish the goal of broadening the number of individuals with private long term care insurance and preventing the need for these individuals to spend down to Medicaid eligibility.

Neither will the projects be able to accomplish their goals if insurance companies continue to use restrictive underwriting practices and deny coverage to those most at risk of needing long term care. Both insurers who submitted proposals to the Commonwealth of Massachusetts expressed serious reservations about covering everyone who applies for insurance under the public/private partnership. Both of these insurers pointed out that the group that applies for insurance will be less affluent and in poorer health than the elderly population as a whole. This happens for two reasons. First, those most at risk of needing long term care, and therefore most interested in purchasing insurance, have lower incomes. Secondly, other insurers will be able to market policies exclusively to a lower risk population, and therefore will be able to offer more attractive premiums to that population.

If the public/private partnerships reject some of those who seek insurance, then it is questionable that the partnerships will be protecting significant numbers of individuals from exhausting their assets and qualifying for Medicaid. On the other hand, if the partnerships are willing to insure everyone who applies, premiums will increase above current market rates, and enrollment will be limited because of affordability and because those who are in better health will seek cheaper insurance.

For all of these reasons, it seems unlikely that the public/private partnerships will be able to overcome the serious affordability and underwriting obstacles to expanding private long term care insurance coverage. At a minimum, states entering into public/private partnerships have an obligation to establish high standards for the private insurance policies to ensure that purchasers receive the benefits for which they have paid. Such standards should include prohibitions against underwriting; high minimum loss ratios; a minimum package of services that includes custodial nursing home care and home care services; prohibitions against prior institutionalization restrictions; inflation protection; and strict regulation of marketing practices.

THREATS TO MEDICAID BENEFICIARIES

The proposed legislation could disadvantage low income Medicaid beneficiaries in a variety of ways: the public/private partnerships could cost states money rather than save money; and public/private partnership participants could receive more favorable treatment from the Medicaid program than other Medicaid beneficiaries. Public/private partnership participants could have higher incomes; be allowed to keep more money for personal needs; and could displace other Medicaid beneficiaries as they compete for nursing home beds.

The theory of the public/private partnerships is that linking purchase of private insurance to Medicaid eligibility will encourage individuals to purchase private insurance. Fewer individuals would then transfer their assets to their children in order to qualify for Medicaid long term care benefits in the future. If the policies are unaffordable for large numbers of seniors or if large numbers cannot qualify for private insurance coverage, the public/private partnership approach will not produce the promised Medicaid savings.

The federal government must scrutinize state estimates of savings to determine if the estimates are based on reasonable assumptions. There is a strong likelihood that these state projects could end up costing states money rather than achieving Medicaid long term care savings. The Commonwealth of Massachusetts developed estimates in 1988 that showed the public/private partnership costing the state money until the year 2000.

If states are allowed to spend Medicaid funds on these projects in any one year, there is a risk that promised savings will not materialize in the future, resulting in scarce Medicaid dollars being spent to help more affluent seniors purchase private insurance. Ironically, this is most likely to happen in states that are attempting to address the affordability problem by subsidizing insurance premiums for lower income seniors. Such an approach requires significant expenditures in the early years for theoretical savings in the next century. H.R. 2499 would commit the federal government to finance the promised Medicaid eligibility and any premium subsidy for the lifetime of the individuals who participate in the public/private partnership.

Many seniors have income and asset levels just above current Medicaid eligibility limits. Approximately 19 percent of the elderly have incomes betwwen 100 and 150 percent of the poverty guideline. High pressure marketing tactics could easily convince these low and moderate income seniors to purchase policies at great financial sacrifice. At least four million seniors already hold duplicative and unnecessary Medigap policies. It would be tragic for low and moderate income seniors to scrape together their limited dollars to participate in the public/private partnership when there is a strong likelihood that medical expenses will consume enough of their resources so that they qualify for Medicaid by the time they need long term care.

Recent research by Korbin Liu and others, using Connecticut and national data, indicates that far fewer nursing home residents spend down to Medicaid eligibility than had been estimated previously. This research found that it is more common for individuals to spend down to Medicaid eligibility because of medical costs incurred while they are in the community, than once they enter a nursing home.*

Other aspects of H.R. 2499 threaten the integrity of the Medicaid program and the low income population it is designed to serve. The legislation would allow the Secretary of Health and Human Services to waive virtually any requirements of the Medicaid program necessary to implement up to ten states' proposed public/private partnerships. Granting the Secretary such broad authority could compromise the Medicaid program's commitment to placing highest priority on meeting the health and long term care needs of low income persons. At least some of the states proposing public/private partnerships intend to implement their programs in ways that would favor more affluent seniors relative to other Medicaid beneficiaries.

At least one state is proposing to waive Medicaid income eligibility requirements for persons who have purchased and used approved private long term care insurance. For the first time, the Medicaid program would be giving preferential treatment to a group of higher income individuals. Spousal impoverishment legislation allows married seniors needing Medicaid long term care to keep up to $60,000 in assets. There are good reasons for

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*Linda J. Schofield, Christine Pattee, and Korbin Liu, "Data Set the Stage for Policy Decisions," **Business and Health**, August, 1988 and Korbin Liu, Pamela Doty, and Kenneth Manton, **Medicaid Spenddown in Nursing Homes and the Community**, unpublished paper, March 1989.

allowing seniors needing long term care to protect some of their assets, but there is no reason why seniors with enough income to pay for long term care out-of-pocket should ever become eligible for assistance through the Medicaid program.

Several states have proposed that individuals be induced to participate in the public/private partnerships by allowing them to keep more of their income once they qualify for Medicaid long term care than Medicaid usually permits. Medicaid law requires that states allow individuals to keep a minimum of $30 a month for personal needs and many states allow only the minimum. States currently have the authority to increase the personal needs allowance to any amount, but not for just a subset of Medicaid beneficiaries. If states believe the current personal needs allowance is inadequate, then all Medicaid beneficiaries should be allowed to keep an increased amount of income.

State Medicaid long term care benefits vary considerably. The demographic characteristics of Medicaid long term care beneficiaries vary significantly as well among states. In 21 states there are seniors who are unable to afford long term care, but who cannot qualify for Medicaid. In those states, individuals with incomes above a set dollar amount do not qualify for Medicaid nursing home benefits, even if their income is less than the cost of nursing home care. It would certainly be unfair to allow more affluent individuals to qualify for Medicaid eligibility through public/private partnerships in these states.

A few states have acted to make sure that nursing homes do not discriminate in admissions against Medicaid beneficiaries in favor of private pay patients. In most states, however, privately insured patients receive preferential treatment. In those states, the public/private partnerships could exacerbate this unfair competition.

CONCLUSION

Medicaid demonstrations are customarily conducted in limited geographic areas for a limited period of time to determine the effectiveness of an experimental approach to providing benefits to low income persons. This legislation would allow the federal government to use scarce Medicaid dollars to encourage purchase of private long term care insurance for a potential 9.4 million elderly persons, or about one-third of our nations seniors. The federal government would incur a permanent obligation to provide Medicaid long term care benefits to all individual participants in the public/private partnerships.

This legislation proposes involving the federal government in a very risky undertaking. There may be a couple of states in which it makes sense to experiment with public/private partnerships under very specific terms. Instead of granting the

Secretary of Health and Human Services broad authority to waive Medicaid requirements in up to ten states, the federal government should be evaluating individual states' proposed public/private partnerships and approving the few that offer the most potential, given the characteristics of the Medicaid program in those states. Under no circumstances should waivers be approved without strict and specific standards for the qualifying private insurance. Neither should any waiver allow public/private partnership participants to be treated more generously than other Medicaid long term care beneficiaries, except for treatment of assets.

Mr. Towns. Thank you.

Mr. Thompson.

STATEMENT OF LAWRENCE H. THOMPSON

Mr. Thompson. Thank you.

I am pleased to report on our project to coordinate both the Government and consumers could benefit from an expanded long-term insurance market. The Government can benefit if middle income elderly no longer rely on Medicaid for assistance in paying for extended long-term care service, and consumers can benefit by delaying or avoiding the financial hardships that so often result from catastrophic long-term care costs.

However, many long-term care insurance policies are deficient in such matters as coverage, eligibility for benefits, and inflation protection. Further, policy tend to be too expensive for most elderly to purchase.

The Robert Wood Johnson Foundation gave planning grants to eight States to address the concerns about costs of long-term care and the limitations of insurance coverage. The proposed demonstration projects we will discuss today are an outgrowth of these planning grants.

While the projects vary significantly, most propose allowing persons who purchase a qualifying private long-term care policy to become Medicaid eligible after the policy pays for a period of long-term care costs. Participants would not have to "spend down" or deplete as much of their assets as is now required to meet Medicaid eligibility thresholds. Implementing the projects, however, requires that the Department of Heath and Human Services [HHS] be given legislative authority to waive certain Medicaid requirements.

We believe that the proposed projects could significantly reduce the financial hardships that some elderly endure as a result of catastrophic long-term care costs. Additionally, the projects could provide a key source of information on the use of long-term care services experienced by project participants. This could help State regulators develop, one, better standards and oversight mechanisms to increase consumers' protection and, two, educational campaigns to inform consumers of the appropriate role of long-term care insurance options.

On the other hand, risks are involved if the Congress gives HHS authority to implement projects that link private insurance coverage with Medicaid. The Medicaid program could experience cost increases, while consumers risk not receiving the benefits they expected.

Any problems that might arise can have significant effects, because the eight States with planning grants account for nearly 45 percent of all Medicaid expenditures nationwide. Further, while the projects are considered demonstrations, their commitments to project participants may require that they operate for 20 or more years. Such a long operating timeframe is more characteristic of programs than of demonstrations. Consequently, authorizing the demonstrations would represent a significant policy decision.

I briefly mention the nature of risk involved in this making that decision and the nature of decision to minimize these risks. We see the need to minimize the risks of Medicaid cost increases. The demonstrations should not simply become vehicles for higher income persons to protect their assets through involvement in this program. The risk of this occurring could be significant because long-term care insurance is presently affordable to only a relatively small number of elderly persons with higher incomes.

For example, a recent study examining the cost of policies from nine companies found that policies offering a basic range of services averaged in excess of $1,300 for a 67 year old. Policy prices escalate with a person's age, and by age 77 premiums averaged $3,200. Reportedly, less than 20 percent of persons between the ages of 65 and 79, the target market for most long-term insurers, could afford such policies.

If higher income individuals predominate among the projects' participants, they could add to Medicaid rolls and hence to overall Medicaid costs.

For one project reviewed, such risks were particularly significant because over 70 percent of the participants are expected to be higher income persons (that is, have incomes more than five times the poverty level). Projects that mitigate this risk are those that incorporate features to, one, make insurance more affordable to lower income persons and, two, limit the amount of assets that individuals can protect from Medicaid's spenddown requirement.

Second, we must be sure States should be required to adopt existing regulatory standards. These projects would involve the States in an activity that itself has risks—promoting long-term care insurance products.

These are relatively new products that are evolving rapidly—often more rapidly than States' regulatory and oversight mechanisms. As little as 2 years ago, for example, many long-term care insurance products included provisions, such as the exclusion of coverage for Alzheimer's disease, that today are widely viewed as overly restrictive.

Because the projects will involve States in promoting private long-term care insurance products, States that seek the necessary Medicaid waivers will assume an even greater regulatory responsibility than other States. For the projects we reviewed, the State will provide a seal of approval to the policies of insurers electing to participate.

States will also undertake advertising campaigns to encourage the purchase of these products. Given these circumstances, should subsequent problems arise with the products because of such factors as coverage restrictions or an insurer's financial difficulties, project participants may look to the States to provide the coverage that was expected of the insurer.

Accordingly, we believe that any legislation authorizing these demonstrations should stipulate that a State demonstration to HHS, prior to being granted necessary waivers, that its laws and regulations meet at least the National Association of Insurance Commissioner's [NAIC's] minimum standards and that it has the capability to enforce them.

States should provide adequate consumer education. By virtue of their involvement in the promotion of private long-term care insurance, States would also assume added responsibilities to ensure that consumers understand any risks associated with the policies offered under these projects. The policies could lessen, but may not eliminate, an individual's risk of impoverishment as a result of catastrophic long-term care costs.

For example, consumers who choose to participate in such projects by buying approved long-term care insurance would continue to be at risk for high out-of-pocket costs. These could include payments for services not covered under their insurance policy, or the difference between what the policies pay and billed charges.

Additionally, individuals would need to understand that the added protection afforded by the projects will only continue as long as they maintain their long-term care policies in force. If an insurer elects to increase long-term care policy premiums in the future, existing NAIC standards allow it to do so on a class basis.

If a policyholder is unable to continue paying these increased premiums, he or she would lose coverage, along with their entire prior investment in premiums. Thus, we believe that any legislation authorizing these demonstrations should stipulate that a State demonstrate to HHS, prior to being granted necessary waivers, that it will provide the information and counseling consumers need to make informed decisions.

Adequate data collection should be required. Further, States would need to collect and evaluate substantially more data than is now routinely collected through their oversight programs to, one, adequately monitor insurers' compliance with regulatory standards, and, two, assess whether the demonstration projects are successful.

Heretofore, much of the information needed to assess the adequacy and role of private long-term care insurance in a public-private partnership has been unavailable, except to the insurers. Such information would include demographics of policyholders, the numbers of persons denied coverage or benefits, and the numbers of and reasons for policy cancellations.

These kinds of data are essential, for both the private sector in developing the long-term care insurance market and the public sector in instituting appropriate regulatory controls. Thus, we believe that any legislation authorizing these demonstrations should stipulate that a State demonstrate to HHS, prior to being granted necessary waivers, that States and insurers have agreed to, one, collect sufficient data, and, two, share all research and tracking data on program participants with HHS. In this way, HHS can monitor the projects and the data can become a matter of public record.

In summary, the proposed projects could reduce the financial hardships that some elderly endure as a result of catastrophic long-term costs. On the other hand, risks would be involved if the projects are given authority to link private insurance coverage with Medicaid.

Consequently, if the Congress wishes to give HHS authority to approve demonstrations such as those proposed by the Robert Wood Foundation grantee States, it should consider including in the legislation statutory requirements to minimize the financial risks to the Medicaid program and to consumers and requirements that the Secretary of Health and Human Services prepare interim reports to the authorizing committees on whether the statutory requirements are meeting their intended purposes.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions you may have at this time.

Mr. WAXMAN. Thank you.

Mr. Tallon, over the past year the Subcommittee on Oversight and Investigations under the leadership of Chairman Dingell had looked into private long-term insurance. They have investigated the operations of individual companies.

The subcommittee's findings were presented in a hearing on May 2 of this year. The subcommittee found among other things that the NAIC standards on which this bill relies are grossly deficient.

The subcommittee found that the NAIC standards contained no explicit consumer protection like those found in the need gap area, false advertising, sale of duplicative policies or abusive practices; contain no protection against unlimited increase; underwriting that results in a denial of coverage to individuals likely to need long-term care; contained no requirements that the insurers prove their solvency or guaranteed benefits; contained no insurance against forfeiture of benefits.

Based on the subcommittee's findings, I prepared a set of questions relating to the standards for the private insurance products that would be linked to Medicare. In addition, the Congressional Research Service at my request has prepared a number of questions relating to the theory and mechanics of the proposal.

I would request that you respond for the record on behalf of the RRJ project. I would appreciate it if you would respond in two ways.

On Monday, we heard from the National Governors Association, National Conference of State Legislators and other State witnesses. They were unanimous in their opposition to the Medicaid initiatives pending before the subcommittee, which would require the States to expand coverage for low income pregnant women and children.

This morning the States are coming before us to ask for a new category for individuals who buy private long-term care insurance.

After receiving benefits under these policies for a specified amount or a specified period of time, these individuals would then be eligible for Medicaid nursing home and home care without having to spend down their assets to $2,000 like other Medicaid beneficiaries. In fact, Medicaid could be making a market for private insurance products designed to help individuals protect assets.

We see the States saying we don't want to spend more on low income pregnant women and infants but we do want to spend on a program to protect the assets of the elderly who will buy long-term policies. This is bizarre.

Shouldn't this be providing basic health care coverage for the poor? Why do we protect assets of the relatively speaking affluent elderly? Shouldn't we plug the loopholes in current law to allow them to avoid the spend down rather than allowing them to buy asset protection from Medicaid?

Mr. TALLON. Mr. Chairman, let me start at that last point, if we are to move directly to avoid the need to do the spend down, then we are, in fact, proposing to differentially have a more generous eligibility requirement for the elderly for long-term care than we would for others under the program.

If there are more resources available under the program, then I think you and I both feel it ought to be moving toward those generally poor.

I think it is for that reason that you question this and that is where we have to see if we can come together.

First, as you know, I have been a strong advocate in other venues of expanding coverage for the poor. When we come to this question, your observation or your question implies that we are creating a new eligibility.

I simply don't believe that is true. I walked through these same series of questions before being able to sponsor the bill in the State of New York with which the same philosophical attitude you bring to the question. My answer was the following: The way Medicaid eligibility for long-term care services works right now, if you happen to be the individual who is required to need the services, if the finger of fate falls on you, you are required essentially to spend what you have and then become eligible for Medicaid.

All that we are proposing is that among all the people who fall within that category, rather than each person being at risk when illness strikes for what is, in effect, a 100 percent deductible, pay everything that you have up front, all that we are allowing, without changing the philosophy of the program is to allow those individuals who otherwise are individually totally at risk to share that risk by pooling it through an insurance mechanism.

I don't believe we have crossed the philosophical ground because in the aggregate all that is occurring is that the individual risk for asset forfeiture that exists under the current program is now being spread through an insurance mechanism to elderly people.

I think we have come up with a more humane way of dealing with what is a very practical problem for your constituents and mine in dealing with the current program. We will certainly try to respond and the directors of the individual programs will respond to individual questions.

As I indicated in my testimony, our proposal is for a series of demonstrations. I would urge us not to try to solve every problem in the world in a demonstration project because I believe our limited knowledge raises serious questions about how far we ought to go. But I would caution you, sir, and the members of the committee in looking at problems that are alleged to exist or do exist currently within the long-term insurance market and apply those problems to the kinds of problems to the programs that will be authorized and certified under this program.

Mr. WAXMAN. If we have a limited amount of Medicaid money in addition to spend, which is questionable given all the summit and the deficit reduction talks, should we take that money and use it for elderly people who are not yet poor enough but may become poor or should we use that money for those who are clearly poor women and children to cover them for prenatal and infant care.

Mr. TALLON. My priority all along has been to support the initiatives taken with respect to pregnant women, children and those who are generally poor. I would wonder whether that is the issue before us in these demonstrations.

First, it is clear that we adopt a standard of budget neutrality. We are not proposing to cost additional money under these programs. We would even indicate our extensive review of the New York data and indicate the potential for a significant public sector savings on long-term care by going with this approach.

I do not assert that with all the programs. I don't think we face the either/or question. If we did, I would not necessarily be advocating so strongly.

But we have a real problem in long-term care. We see it every day in the current operation of the program which is largely unsatisfactory to the participants to have to disperse a large amount of assets and their income.

I think we should come up with a mechanism here of allowing them to pool that risk without raising the either/or questions implicit in your questions.

Mr. Waxman. Thank you.

Mr. Towns.

Mr. Towns. Senator Tallon, can we safely say that the kind of managed care model which you are proposing still gives seniors quality care without a loss in services?

Mr. Tallon. Mr. Towns, I think what is proposed here is going to be an improvement with respect to service delivery. I would turn to Associate Commissioner Shapiro of New York Medicaid.

Ms. Shapiro. I would also like to respond to the chairman's previous question. Then I will add to that.

Mr. Waxman. Let me recommend that you respond to Mr. Towns' because each of us has 5 minutes.

Ms. Shapiro. You mean if there are three choices of services, you mean we will only deal with well established companies in New York State that will guarantee the policies and there will be no diminution.

When you go in as a private patient, you have a better chance of getting in because nursing homes discriminate against those on Medicaid. I think the critics of the private public partnership are well intended. Some, I think, may be submerged in think tanks if they are saying this is a new class of middle class people who are going to be subsidized.

I get invited to do seminars on estate planning. You see hundreds of lawyers who are looking to protect their assets. This is by people who are formerly middle class.

We are proposing to substitute the insurance dollar with the public dollar to free up protection for the poor people.

I am from east New York, Congressman Towns. It was poor when I was there and it is poor now. Senator Tallon and I are concerned about preserving the funds for the poor and that is why we support this.

Mr. Towns. One of New York State's concerns is providing long-term care to seniors without forcing them to expend all their assets before they are eligible for Medicaid.

Shouldn't we provide these programs as a means of giving the elderly some dignity as well as assurance on the availability of long-term health care?

Mr. Thompson. My Agency is not opposed to somebody trying a demonstration to see if it is possible to improve the long-term care product and make sure it is available to the largest sector of the population. This product is still evolving. There are many concerns about how adequate it is, about people who buy it thinking they are protected and discover they are not protected when an event occurs. What triggers the payments? How we handle inflation? What is going to happen when the prices rise and individuals who have perhaps been paying for 20 years decides they can no longer afford it so they stop paying and on the 21st year they need long-term care and they are not insured?

These problems need to be worked out. I am not saying they cannot be worked out. I see a set of proposals that are vague as to how they are going to be worked out, and who is going to be sure they are worked out and in the interests of the consumer.

The gist of our concern is that there needs to be adequate protection here to be sure that we don't end up with the Government selling large numbers of policies that do not deliver the protection promised.

Mr. Towns. Is that the reason why you use that statement price?

Ms. Torda. The reason I use it is because the policies are expensive. It doesn't look as if the projects will be able to insure us or to lower premiums. That means only the upper echelon of seniors will be able to afford those policies. If that is true, those seniors will not be likely to spend down to Medicaid any way. So very many additional persons will not be able to afford the policies through the projects. The projects will not say Medicaid funds because those likely to spend will not buy the policies and will be kept off the Medicaid program.

Mr. Towns. I yield back—I don't have to yield.

Mr. Waxman. Did you want to respond to his question?

Mr. Towns. I was going to ask the assemblyman if he would agree with the comment made that most people would not be eligible as a result of it? The people who would need it would not be able to benefit from it?

Mr. Tallon. Mr. Towns, I don't. I think you do a demonstration. I think there may be the potential for a larger number of people to be willing to benefit in order to be able to take the advantage of the policies and ultimately the Medicaid eligibility.

I have a feeling from my own grassroots experience that the higher I go up the income scale, the more likely I am to find individuals who have availed themselves of the kind of legal advice Commissioner Shapiro talked about. I am really less concerned I am creating some great benefit for the wealthy. I think I may be opening a path for a system that works better than the current one.

The current system doesn't work very well, and the question is which is the best of the alternatives with respect to improving the current system?

Mr. Towns. Thank you, Mr. Chairman.

Mr. Waxman. Thank you, Mr. Towns.

Mr. Nielson.

Mr. Nielson. I have no questions. I yield more time to Mr. Towns.

Mr. Waxman. I want to start off the second round.

We, in effect, are going to start down the road of the Government reinsuring private insurance, and saying to private insurance, you don't have to worry about having to protect this person for long-term care for the remainder of their lives if it is too long a period of time, you can take your chances on covering somebody for 2 years and after that, you will know that you only have to pay for 2 years, and then the State, through the Medicaid program, will pay for the rest of that individual's lifetime.

Donald Trump, who I—even with his misfortunes, would be considered a pretty wealthy man, could buy his parents—assuming they are still alive, into this plan and the Medicaid program, which is the health care for the poor, would suddenly be there to make sure Donald Trump's parents are protected, and maybe their sons if he found his parents needed some help.

Being protected by the health care program for the poor and the beneficiaries are the insurance companies who now have some kind of way to make sure they don't have to pay beyond a certain limit for those people who buy this coverage. It is not a bad idea, per se, but it is of dramatic change in the Medicaid program, which was set up to protect the poor.

I guess that is what is bothering me. Ms. Torda, you looked at this. You raised some of these same concerns as well. We don't have standards in place, although Mr. Thompson suggested we get some standards in this bill and make sure we have got some insurance companies that aren't fly-by-night insurance companies.

The fundamental question is, should the Government start making sure the middle class and wealthy are going to be given a lower rate for their long-term insurance by using the funds for the health care program for the very poor?

Ms. TORDA. Mr. Chairman, not only is there that broad theoretical concern, but the projects are requesting specific ways in which the Medicaid program should treat these partnership participants more favorably. They should be allowed to keep more money for their personal needs once they get in the nursing homes than regular Medicaid beneficiaries.

The State raised that, but the partnership proposals are saying we don't treat Medicaid beneficiaries very well in nursing homes. If we want these people to buy insurance, we are going to have to promise them, particularly, special treatment in the nursing home.

Mr. WAXMAN. They will get special treatment in the nursing homes?

Ms. TORDA. In the nursing homes.

Mr. WAXMAN. In Mr. Towns and mine—the elderly in our districts get Medicaid after they are most likely in the nursing home, maybe even before. If they are poor before they get in the nursing homes, and often nursing homes don't want to take them. Once they get in the nursing home, whatever assets they have, they end up having to exhaust them. I think that is a terrible thing we do in our society.

We are not going to use that program for the poor to help people who will get this to nursing homes right away, because they will be more middle class, already privately insured. Once they get in the nursing homes, they will be treated better than our constituents who are poor, they will be given better care.

Everybody should get better care. And third, by the time they pass away, whatever assets they have, which could be any amount of assets, will be passed down to their kids.

When our constituents die, that is the end. In order to get this good deal, they have to be able to pay $3,000 or $4,000 a year for health insurance. I would want to pay that for my father, it is a good deal for people who are middle income and upper income. Not that they don't deserve something better than having to impoverish themselves before they get help, but the fundamental question is, do we take the Medicaid program, which is the health program for the poor, and maybe use that money should people not die fast enough and the State ends up paying for their care, should we take the funds from that program that we struggled to increase in little increments to cover more low income people, and start using it for middle income people?

Is the fundamental problem on your mind as well?

Ms. TORDA. Yes, and there is also the underwriting issue that the partnerships will not really be able to offer equal protection to those who apply to participate in the partnership.

Even if moderate income seniors wanted to buy the insurance, they would probably get excluded to some degree from participating in the program, because they are more likely to have health problems. Those who apply for the partnership insurance will be poor and have greater health problems.

Mr. WAXMAN. Not everybody will be able to buy this insurance plan. We say we will make it available to anybody, but it won't be available to anybody, because insurors who have their tailend covered by the Government will seek out those who will not be high risk to them until the Government comes into play and they will look for people who don't have medical problems to start with, and they go out and buy this insurance or represent a lower risk or whatever other criteria they want to use.

I understand what you are doing. I also represent a lot of middle income people, and I know what a tragedy it is when you are faced with a possible long-term care problem that is just not covered by Medicare, and for the most part, people have trouble buying these private insurance policies because they are not readily available.

I want to share this story: I remember reading Business Week a number of years ago where Business Week advised their people on how to make sure they could shelter their assets so Mom and Pop can go to the nursing home paid for by the public expense.

And I can understand why they would want to do that, and we are not talking about people who are often super rich, they are not real affluent and there are a lot of heartaches, but I felt that is wrong if you have a program for the poor, you use it for the poor.

I believe, however, that we need to establish a Federal level program to protect all people for long-term care needs. And while we are moving in that direction, do we patch up with this piece which wouldn't be there for everybody, but only for some who are low risk and can afford it.

That is what is on my mind, and I gather the answer to that is it is a demonstration, let's see how it works. My time has expired. Do either of you want more time?

Mr. Tallon, you look like you are anxious to say something.

Mr. Tallon. Mr. Chairman, thank you for the opportunity just to offer one final comment. This comparison between a Medicaid program that is just for the poor and these alternatives, sir, respectfully is not a description of the current Medicaid program. The current Medicaid program protects assets with respect to people who are in nursing homes, and Congress has taken some steps with respect to spousal impoverishment, for example, to acknowledge there are different circumstances.

The current program is not one that has this position of only——

Mr. Waxman. Just a second. Isn't there a big difference in saying we want to protect the ability of a spouse in a nursing home to be able to share some of the assets with the spouse at home? Isn't that a different situation than saying we will let Mr. Trump's parents be protected?

Mr. Tallon. Yes, sir, there certainly is.

Mr. Waxman. We do have limits.

Mr. Tallon. That is right. The only point I am making, as the Congress has dealt with the reality of that situation, it has not rededicated a Medicaid program that is purely aimed at those who are only the low income poor. There is a mixed program out there right now.

Therefore, I don't believe we are entering into a new philosophical ground here. There is not, sir, a transfer of assets or, in the aggregate, there is not a transfer of wealth here away from the poor, because those insurance premiums can only ultimately pay benefits, roughly equal to what income they take in.

We are not taking money away from the poor. We are working within a group of people who currently get eligible for the Medicaid program by a particularly painful and circuitous route.

Mr. Waxman. We do if people live longer and once they get in nursing homes and the Government comes in and starts paying their bills, then we are spending Medicaid dollars for these people. If Government funds are used—and I guess everybody is hoping people will die before those Government funds need to be used—everybody except the family members—but when those Government funds are used, if they are being used for this, and we have to, every year, live within tighter and tighter budgets, they are not going to be available for other things.

Mr. Tallon. Mr. Chairman, the benefits are going to be based on actuarial estimates what is likely to occur. The reason for doing demonstrations is so we can better understand what the actual risks is going to be. The question of risk and how much we will be exposed to is going to be there when we keep the current system with no change, whether we do these demonstrations or move to a totally public funding system.

All those questions will still exist. There is a limited change in a demonstration context.

Mr. Waxman. I appreciate what you are saying, and the differences we have. I have enormous respect for you, Mr. Tallon, and I know your commitment is there for the poor and the Medicaid program, because you have been a champion in that area.

I want to thank all of the witnesses, and we may have additional questions, and we would like you to respond for the record if any member wishes to submit questions to you.

We will recess now until 2 o'clock, and reconvene in this room at that time.

[Whereupon, at 1 p.m., the subcommittee recessed, to reconvene at 2 p.m., the same day.]

AFTER RECESS

Mr. **Waxman**. The hearing of the subcommittee will come to order.

This afternoon's panel will discuss the issues raised by Senator Pryor and Congressman Cooper this morning. This is not a luxury that the underfunded Medicaid program can afford.

As many of you well know, this subcommittee has been long concerned about ultrahigh prescription drug prices that result in excessive profits to drug companies. We held hearings on this issue in 1985. At that time, prescription drug prices were increasing by roughly twice the Consumer Price Index.

We looked at the issue again in 1987. By then, prescription drug prices were increasing by 4.5 times the CPI. More recently, we are seeing a new phenomenon. Some drugs are costing $10,000 or more per patient each year.

In February of this year, we heard testimony on three ultraexpensive drugs that had managed to qualify for the benefits of the Orphan Drug Act, which was intended for drugs that could not make a profit.

Today, we are looking at a situation in which Medicaid finds itself paying ultrahigh prices for drugs while private purchases and other public purchases receive substantial discounts.

Representatives Wyden and Cooper have just introduced legislation, H.R. 5589, which would give Medicaid most favored nation status in the purchase of prescription drugs.

This afternoon's panel will discuss the disadvantage which Medicaid now finds itself in, and the solution proposed by this legislation.

Jim Parks is chief of the Medi-Cal Drug Discount Program. John Zabriskie, president of Merck, Sharp & Dohme. Gerald Mossinghoff, president, Pharmaceutical Manufacturers Association. Robert Ingram, executive vice president, Glaxo. Ronald Ziegler, president, chief executive officer, National Association of Chain Drug Stores. John Rector is vice president of the National Association of Retail Druggists. John Gans, executive vice president of the American Pharmaceutical Association. Dr. Lonnie Bristow, member of the board of trustees of the American Medical Association. Sara Rosenbaum is director of programs and policy of the Children's Defense Fund.

I want to thank all of you for appearing before our subcommittee this afternoon. We appreciate your willingness to review and prepare to discuss the Wyden-Cooper bill in such a short timeframe.

Without objection, your written statements will be included in the record. However, in order to keep the volume of written material within reasonable bounds, I will reserve the right to excise from the record those materials that relate exclusively to S. 2605, a proposal not before the subcommittee.

I understand there will be a hearing this coming Monday in the State on the Pryor bill, and that would be the appropriate forum for comments that relate exclusively to S. 2605.

Mr. Wyden has to catch a plane later this afternoon. I know he wants an opportunity to ask questions of each of you. So, I am going to ask that for the oral presentations, that you limit your presentation to us to no more than 5 minutes, and I have to be very strict in that regard.

We will start with Mr. Parks first, if we could have the microphone passed over to him.

STATEMENTS OF JAMES PARKS, CHIEF, MEDI-CAL DRUG DISCOUNT PROGRAM, CALIFORNIA DEPARTMENT OF HEALTH SERVICES; GERALD J. MOSSINGHOFF, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; JOHN L. ZABRISKIE, PRESIDENT, MERCK, SHARP & DOHME; ROBERT A. INGRAM, EXECUTIVE VICE PRESIDENT, GLAXO, INC.; RONALD L. ZIEGLER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL ASSOCIATION OF CHAIN DRUG STORES; JOHN M. RECTOR, VICE PRESIDENT OF GOVERNMENT AFFAIRS AND GENERAL COUNSEL, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; JOHN A. GANS, CHIEF EXECUTIVE OFFICER, AMERICAN PHARMACEUTICAL ASSOCIATION; LONNIE R. BRISTOW, MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION; AND SARA ROSENBAUM, DIRECTOR OF PROGRAMS AND POLICY, CHILDREN'S DEFENSE FUND

Mr. Parks. My name is Jim Parks. I am chief of the Medical Drug Discount Program. I appreciate the opportunity to be here and represent at least California.

I don't believe I am qualified or even authorized to represent all Medicaid agencies, so I wouldn't try to do that. I will, however, in a couple of my comments, represent comments made to me by the Medicaid agencies.

I would, first of all, like to acknowledge the very important contributions made by Senator Pryor and his staff early in this year, in their efforts to identify and bring attention to the problem of Medicaid reimbursement for pharmaceutical products.

I don't believe without that involvement at the Federal level, California would have been able to succeed in its efforts legislatively this year. We were, however, successful in getting legislation authorizing a drug discount program.

We would like to express support for the concept of Federal involvement in this area for a couple of very important reasons.

One is, we believe it will ensure the continuation of States' progress and ability in achieving discounts. And, two, we believe it will assure that States without the bargaining strength that some of the larger States have will also be able to achieve discounts.

I would like to share with you just very briefly the status of California's drug discount program. To date, we have four signed contracts. Those contracts that we have signed are with Merck, Sharp & Dohme, Glaxo, the Sirl Corp. and the Syntex Corp.

Additional, we have three additional agreements that we have reached. Consensual agreements on that are yet to be signed, and we have four more formal negotiations scheduled with an additional four meetings, what we called preliminary meetings scheduled with other companies.

Of the seven contracts we reached agreement on, six of those seven resulted in net savings to the medical program. We are proud to point out we have agreed in those contracts to the addition of 15 drugs to the medical drug formulary, which we now refer to as a list of contract drugs that we did not previously have and an additional five dosage formula in strength of drugs that were already represented.

I believe our success so far is attributable to several factors. One is the Federal interest that has been expressed. Two, because of the size of the medical market in terms of the beneficiaries and the number of prescriptions, the medical program last fiscal year ending June 30, processed approximately 31 million pharmacy prescriptions at a cost of approximately $372 million for the ingredient cost only of those drug products.

Another contributing factor, I believe, is medical use of drug formulary, which we now refer to as a list of contract drugs. Med-Cal has a semirestricted drug formulary. Those drugs not on the list of contract drugs are available through a prior approval process.

We also believe manufacturers see contracting as an opportunity now within the medical program to add drugs that they previously were unsuccessful in adding, and to add them at a quicker rate than they had been in the past.

In our prior administrative process, it took a minimum of 14 months and an average of somewhere between 3 and 4 years, even if we wanted to, to add a drug. With contracting, we can now do so within 90 to 120 days.

I would like to address the issue of Federal legislation, and then leave it open for discussion later.

First of all, California believes that Federal legislation is both appropriate and probably necessary. There are, however, two aspects to Federal legislation.

One is areas of potential savings and the other is areas of potential cost. Areas where we see potential savings occurring are the concepts of requiring minimum aggregate savings by States of a predetermined level.

Another area of potential savings, I believe, is allowing those States who have formularies to retain those formularies.

A third area of savings I think is to give those States who, because of their size or low volume activity, the ability to directly become part of a contracting consortium at the State or Federal level.

All those, I believe, offer opportunities for Medicaid agencies to reduce their medical drug expenditures. There are, however, some potential cost areas that I have seen in discussions about drug coverage in the Medicaid programs.

One is requirement for open formulary. California is very concerned about the cost of an open formulary. We have projected costs in excess of up to $400 million for an open formulary in California. There are many other States who also employ formularies. Those represent potentially severe increases in cost we have seen posed for statewide utilization programs.

Conceptually, we think it is a good idea, but how those programs are implemented can cause some concern in terms of potential costs. We have seen proposals for increases in pharmacy reimbursement. Those represent potential increase of cost.

In California, we estimate that every 1 cent increase in pharmaceutical reimbursement will cost approximately $300,000.

Finally, there have been some proposals to capping the amount of money available to Medicaid agencies. I am not sure that is a good idea. Some of our current contracts have resulted in savings of over 50 percent.

In the interest of time, I will conclude my testimony.

[Testimony resumes on p. 572.]

[The prepared statement and attachments of Mr. Parks follow:]

PREPARED TESTIMONY BEFORE THE

HOUSE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT

SUBMITTED BY JAMES PARKS

SEPTEMBER 14, 1990

CALIFORNIA MEDI-CAL DRUG DISCOUNT PROGRAM

Mr. Chairman and committee members, I am Jim Parks, Chief of the Medicaid (Medi-Cal) Drug Discount Program, for the California Department of Health Services. I am here to make a brief presentation regarding California's recently enacted legislation authorizing a drug discount program and to provide general information about the status of the program.

I would also like to provide some suggestions about what type of federal legislation would assist state medicaid agencies achieve their concurrent goals of obtaining discounts from pharmaceutical manufacturers while also assuring medicaid beneficiaries access to a full range of medically appropriate drug therapies. At the conclusion of my remarks, I will also be available to answer any questions you may have relative to the issue of pharmaceutical drug product discounting.

The Medi-Cal Program pursued the issue of achieving significant discounts from pharmaceutical manufacturers for several reasons:

1. The drug program was one of the fastest growing components of the entire Medi-Cal program.

2. Because of this growth, there was a growing reluctance to add additional drugs to the Medi-Cal Drug Formulary because of the cost implications.

3. The types of discounts available to private health care enterprises and other governmental agencies seemed to offer a way for Medi-Cal to be able to afford to add new drug therapies without necessarily increasing the drug program budget.

4. A review of pharmaceutical manufacturer discount practices convinced us there was no legitimate reason why a state Medicaid agency should not be able to obtain a discount if that was explicitly made a requirement for a manufacturer's product being eligible for reimbursement by the program.

The discounts available to some other governmental agencies ranged from a low of 5-6% to as high as over 100% for some single source products. Allow me to give you a couple of examples: Ceclor 250 mg.tablets, used to treat certain types of respiratory infections, are reimbursed by Medi-Cal for $149.00/100 tablets, Los Angeles County and the Veterans Administration pays approximately $55.67 for the same quantity; Tagamet 300 mg tablets, used for treatment of ulcers, are reimbursed by Medi-Cal for $54.77 for 100 tablets; Los Angeles County pays $38.59 and the Veterans Administration pays $27.65 for the same quantity. Obviously, generically available multi-source products often see even higher discounts made available in an open, competitive environment.

The Department initially proposed drug discount legislation in January, 1989. We were unsuccessful largely because of intensive lobbying by the Pharmaceutical Manufacturers Association and its individual companies, and the absence of active support at any level for the proposal outside the Department itself. However, this year we successfully obtained passage of authorizing legislation.

The major elements of the Medi-Cal Drug Discount Program legislation include:

1. The department's retention of control of a formulary, now referred to as a "list of contract drugs";

2. The continued use of five criteria for the evaluation of drugs for placement on the list of contract drugs - safety, efficacy, essential need, misuse potential and cost;

3. Provisions allowing the department to contract for drugs on a bid or nonbid, and the confidentiality of negotiated contracts from disclosure;

4. The ability of the Department to establish an advisory body composed of experts in individual therapeutic categories, to advise the Department of appropriate drug representation within each therapeutic category;

5. A provision for "grandfathering" drugs already on the list of contract drugs, subject to a negotiated contract (price discount);

6. Provisions for handling drug addition requests which were "deemed denied" to enable the Department to dispense with a very lengthy administrative hearing process;

7. A commitment by the Department to enhance the prior approval process for drugs not on the list of contract drugs, including periodic reports to the state legislature on the overall impact of the drug discount program on beneficiaries, providers, and the savings achieved by the program; and

8. A two year sunset on the provisions of the Medi-Cal Drug Discount Program to enable the state legislature to assess the Department's performance in this area.

Indisputably, an important, integral part of our discussion today should include Medi-Cal's use of a drug formulary. Generally, a drug formulary is a list used to identify preferred drugs that are covered under a given health care program. For many years, hospitals, private health care programs, and governmental health agencies throughout the country have been using drug formulary systems in their administration of pharmaceutical service programs. The purpose of these drug formularies is to improve the quality and control the cost of drug therapy. Since the medical care of patients in any health care organization is often dependent upon the effective use of drugs, the evaluation and selection of specific drugs has become the standard process for providing appropriate and economical drug therapy. The formulary system within hospitals has become so important that such a system is now a requirement or recommendation of Title 22 of the California Code of Regulations, the Code of Federal Regulations, and the Joint Commission on Accreditation of Healthcare Organizations (JACHO.)

As regards the frequently heard allegation that Open Formularies save money, that simply is not the case. I have available and would like to share with you our most recent analysis of this issue. Attached to that is the Department's cost analysis for an Open Formulary in the California Medicaid program.

Perhaps the central fallacy of arguments supporting an Open Formulary is the presumption that all new drugs approved by the FDA equal improvements in health care. First of all, the FDA approves the addition of new drugs to the American market solely on the basis of safety and efficacy. This approval is not contingent upon comparing the new drug that is seeking FDA approval with other drugs of similar therapeutic use. This is why a formulary system is so valuable.

Secondly, the FDA does classify new drugs according to its chemical type and therapeutic potential. I think it is important to point out that of the 348 new drugs introduced by the 25 largest U.S. drug manufacturers between 1981 and 1988, only 12, or 3% of the total were rated type "A", designating these as "Important Therapeutic Gains." Only 44, or 13% were rated type "B", representing "Modest therapeutic Gain." The remainder, 292 or 84% were rated type "C", providing "Little or no therapeutic gain." Within the health care profession, drugs that provide little or no contribution to existing therapies are known as "me-too" drugs. Unfortunately, it is well known that the majority of new drugs are priced significantly higher in most cases than older available medications.

California's formulary is used as the base from which many private health care organizations build their own formularies, and, because of that, pharmaceutical manufacturers have conceded the importance to them of getting their product listed on it. A number of other states also employ formularies for many of the same reasons. More than any other reason, it is the formulary that gives private health care organizations the clout to successfully demand discounts from pharmaceutical manufacturers.

Briefly, I would like to share with you the status of California's Medi-Cal Drug Discount Program. As of September 7, 1990, we have reached agreement on contracts with four manufacturers. Two of those, Merck, Sharp, and Dohme, and Glaxo, Inc., have been publicly announced, we expect to announce the other two within the next few days. These four contracts, cumulatively have resulted in the addition of fifteen drugs to the Medi-Cal list of contract drugs (formerly the Medi-Cal Drug Formulary), two of which are 1A drugs, and four of which fill gaps in drug therapeutic categories. The cumulative cost of the addition of all but one of these drugs is approximately $25,300,000; and the cumulative anticipated savings is approximately $26,731,000 for the duration of the contracts. It is worth noting that the one drug excluded from the above information is the first drug we have added in a new category of cholesterol lowering drugs. The anticipated cost of that one drug, Mevacor, is approximately $20,315,000 over the life of the contract.

As stated earlier, we have concluded contract discussions with another two companies with announcements expected shortly, and we have already scheduled five additional contract negotiations within the next few weeks. All but one of our contracts have resulted in net savings to the California Medicaid program over the term of the contracts.

Our contracts, by state law and manufacturer requests, are confidential in nature, so I cannot reveal the specifics of any individual contracts, however, I can share some general information. Discounts vary from being very low to offers of "best price" on individual drugs; contract length averages in the 3 to 5 year range, and all contracts have resulted in the addition of at least some drugs to the list of contract drugs. All contracts have provisions which assure that discounts do not shrink through the normal process of price increases; and finally, all discounts are achieved through a rebate mechanism that does not require any kind of direct drug purchase and/or redistribution mechanism.

We are aware that many pharmaceutical manufacturers are in the process of developing their own "national" program for reimbursement to medicaid agencies. Common to almost all of them is that for a medicaid agency to be eligible for the proposed discount, they must agree to make available all of that company's drug products. California is opposed to that concept as it violates our strong belief in the appropriateness of a drug formulary. That is not to say we may not, in the negotiation process, agree to add all of a company's existing single source products, or to favorably or expeditiously review new FDA product approvals; just that as a manufacturer's condition of being eligible for a rebate, it is not an appropriate requirement for states with formularies. I would point out that our contracts do not adopt these policies.

Finally, I would like to address the issue of the appropriateness or need for federal legislation. I believe that federal legislation addressing the issue of medicaid agencies achieving some level of discount from pharmaceutical manufacturers is appropriate, and probably even necessary. However, I believe that the following general guidelines may be sufficient, thereby allowing states the latitude to work out individual programs that best meet their needs:

1. All state medicaid agencies should achieve some minimum aggregate level discounts from pharmaceutical manufacturers.

2. States should have the flexibility to have a formulary or not, so long as drugs not readily available remain obtainable through some type of exception (prior approval) process.

3. States with an existing mechanism for obtaining discounts from pharmaceutical manufacturers should be allowed to retain their program so long as they meet the conditions specified above.

I hope that this testimony is helpful. I am available to answer any questions you may have. Thank you.

Examples of Single Source Drugs - Price Paid Comparison

Drug Name	AWP or Direct Price	Medi-Cal Pays	General Services	LA County	Veterans Admin	Lowest	Percent Difference
Capoten 12.5mg Tablet	$32.50	$32.50		$32.50	$28.77	$28.77	13%
Capoten 25mg Tablet	$35.78	$35.78		$35.78	$30.27	$30.27	18%
Capoten 50mg Tablet	$59.65	$59.65		$59.65	$51.58	$51.58	16%
Carafate 1gm Tablet	$50.63	$48.10		$41.70	$28.51	$28.51	69%
Cardizem 30mg Tablet	$70.00	$66.50		$25.00	$17.72	$17.72	275%
Cardizem 60mg Tablet	$48.44	$46.02		$39.90	$28.95	$28.95	59%
Ceclor Pulvule 250mg	$149.08	$149.08		$116.10	$55.67	$55.67	168%
Clinoril 150mg Tablet	$65.61	$65.61	$60.53	$65.61	$58.77	$58.77	12%
Clinoril 200mg Tablet	$80.63	$80.63	$74.38	$80.63	$45.39	$45.39	78%
Compazine 25mg Supp	$22.50	$21.38		$15.04	$11.65	$11.65	83%
Dilantin Infatab 50mg	$9.48	$9.48	$6.93	$8.29		$6.93	37%
Feldene 20mg Capsule	$143.02	$143.02		$143.02	$85.69	$85.69	67%
Geocillin 382 Mg Tablet	$106.68	$106.68			$64.94	$64.94	64%
Glucotrol 10mg Tablet	$36.18	$36.18	$32.20	$33.81	$26.39	$26.39	37%
Glucotrol 5mg Tablet	$19.71	$19.71	$17.54	$18.42	$14.44	$14.44	36%
Halcion 0.25mg Tablet	$36.49	$36.49	$34.10	$35.76	$9.98	$9.98	266%
Haldol Decanoate 50mg/ml Ampule	$230.93	$219.38	$143.00	$151.58	$137.54	$137.54	60%
Imuran 50mg Tablet	$79.32	$75.35		$66.97	$58.96	$58.96	28%
Klonopin 1mg Tablet	$52.72	$50.08			$42.47	$42.47	18%
Lo/Ovral Tablets - 21's	$16.17	$16.17	$1.75			$1.75	824%
Lo/Ovral Tablets -28's	$16.37	$16.37	$1.75	$1.75		$1.75	835%
Lopressor 100mg Tablet	$59.61	$56.63	$39.03	$46.40	$21.49	$21.49	164%
Lopressor 50mg Tablet	$39.31	$37.34	$24.13	$30.32	$11.94	$11.94	213%
Methergine 0.2mg Tablet	$30.90	$29.36		$25.75		$25.75	14%
Naprosyn 250mg Tablet	$60.65	$57.62	$47.67	$49.10	$30.16	$30.16	91%
Naprosyn 375mg Tablet	$77.24	$73.38	$60.70	$62.53	$35.23	$35.23	108%
Naprosyn 500mg Tablet	$95.22	$90.46	$74.83	$77.08	$42.17	$42.17	115%
Ovral-21 Tablet	$21.53	$21.53	$1.75	$1.75		$1.75	1,130%
Parlodel 2.5mg Tablet	$100.98	$95.93	$76.67	$84.17	$60.43	$60.43	59%
Plaquenil 200mg Tablet	$75.73	$71.94		$59.60	$43.11	$43.11	67%
Premarin Vaginal Cream w/ Applicator	$17.29	$17.29	$6.70		$5.47	$5.47	216%
Procardia 10mg	$36.04	$36.04	$25.90	$32.14	$22.45	$22.45	61%
Procardia 20mg	$64.86	$64.86		$57.85	$37.16	$37.16	75%
Retrovir 100mg Capsule	$144.23	$137.02		$121.77	$120.19	$120.19	14%
Sinemet-25/100 Tablet	$38.08	$38.08			$34.84	$34.84	9%
Tagamet 300mg Tablet	$57.65	$54.77	$38.59	$38.59	$27.65	$27.65	98%
Tagamet 400mg Tablet	$58.45	$55.53	$44.20	$44.20	$29.87	$29.87	86%
Timoptic 0.5% Ocumeter 5ml	$10.78	$10.78	$10.17	$10.78	$9.48	$9.48	14%
Tolectin DS 400mg Capsule	$68.92	$65.47		$50.60	$18.54	$18.54	253%
Tri-Norinyl Tablet 28's	$16.30	$15.49		$0.01		$0.01	154,750%
Vasotec 10mg Tablet	$59.83	$59.83		$59.83	$56.68	$56.68	6%
Vasotec 5mg Tablet	$56.97	$56.97		$56.97	$54.03	$54.03	5%
Zovirax 200mg Capsules	$67.09	$63.74		$54.00	$60.45	$54.00	18%

OPEN DRUG FORMULARIES

MYTHS AND MISCONCEPTIONS

Purpose of Formularies

A drug formulary is a list used to identify preferred drugs that are covered under a given health care program. For many years, hospitals, private health care programs, and governmental health agencies throughout the country have been using drug formulary systems in their administration of pharmaceutical service programs. The purpose of these formularies is to improve the quality and control the cost of drug therapy. Since the medical care of patients in any health care organization is often dependent upon the effective use of drugs, the evaluation and selection of specific drugs has become the standard process for providing appropriate and economical drug therapy. The formulary system within hospitals has become so important that such a system is now a requirement or recommendation of Title 22 of the California Code of Regulations, the Code of Federal Regulations, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

> Hospitals, private health care programs, and governmental health agencies throughout the country have been using drug formulary systems in their administration of pharmaceutical service programs for years.

II. California's Medi-Cal Drug Formulary

The Medi-Cal pharmaceutical program maintains the Medi-Cal Drug Formulary, which contains approximately 500 drugs of various types to be used in the treatment of outpatient Medi-Cal beneficiaries at a cost, for just the drugs, of over $500 million per year. The Formulary is semi-restrictive (semi-closed) in nature, like many public and private hospital outpatient programs, but not the completely restrictive (closed) formulary system used in some state Medicaid programs. This difference is significant because a semi-restrictive formulary provides coverage for drugs not listed, whereas a closed formulary does not. In this regard, nearly all commercially available drugs not listed on the Formulary are covered by the Medi-Cal Program, subject to prior authorization from a Medi-Cal consultant. This process insures the availability of medically necessary drugs not listed on the Formulary.

> The Medi-Cal Drug Program spends over $500 million annually. Nearly all commercially available drugs not on the Formulary are covered by the program, subject to prior authorization.

A few drugs listed on the Formulary are restricted to use for certain specified clinical conditions: other uses require prior authorization. Certain drugs on the Formulary that are typically prescribed for long-term use have minimum dispensing quantity requirements. This is to avoid excessive dispensing fees associated with inappropriately small prescription quantities. In order to control inappropriately large prescription quantities, all drugs covered by the program have a uniform maximum dispensing quantity limitation.

The Formulary is kept up to date by the ongoing addition of newer drug products and deletion of older, inferior drug products. These changes take place three times a year, subsequent to meetings of the Medical Therapeutics and Drug Advisory Committee. This Committee is an "outside" advisory group that makes recommendations to the Director of the Department of Health Services (DHS) on changes to the Formulary. The Committee is comprised of practicing physicians.

pharmacists and one pharmacologist. In addition to the Committee, professional staff of DHS make recommendations to the Director after first performing a thorough review of the drugs under consideration. This review includes a review of public hearing testimony, reference to current medical literature, and contacts with physician specialists within the medical schools and private practice settings. The criteria which DHS uses in considering a drug addition or deletion are the drug's relative safety, effectiveness, misuse potential, and cost compared to Formulary drugs, and its ability to fill an unmet need on the Formulary.

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In regard to level of care provided by a formulary system, it is noteworthy that these five criteria provide a mechanism to screen drugs from the Formulary which do not have an overall advantage over existing Formulary drugs. For example, a drug that is equally safe and effective but more expensive than existing Formulary drugs may not be added to the Formulary because the cost disadvantage is predominant.

III. Unsuccessful Attempts to Discredit Restricted Formularies

The Pharmaceutical Manufacturers Association (PMA) has recently sponsored studies of various states' Medicaid programs that have attempted to show that unrestricted or "open" drug formularies are more cost-effective and provide higher quality of health care than restrictive drug formularies such as Medi-Cal. The motivation to do these studies, of course, is not to find ways to save the states' Medicaid programs money, but rather to increase the utilization of the drugs they market, and thereby expand their market share.

> The PMA motivation to do these studies is not to find ways to save the states' Medicaid programs money, but to increase utilization of the drugs they market and consequently, their profits.

One such study is reviewed here because it has been reported to be the strongest study to date of the effects of restrictive formularies on Medicaid expenditures. In order to understand why there still remains no proof to the authors' claims. one must examine closely the methodology and the associated assumptions made. as well as their analysis of the data, and then see how this relates to the Medi-Cal program.

The study to be reviewed here was authored by W. Moore and R. Newman of the Department of Economics. Louisiana State University. It is titled. *An Economic Analysis of State Medicaid Formularies: Implications for the Recent Changes in the Louisiana Formulary.* This study purposes to examine the economic effects of restrictive drug formularies in 47 state Medicaid programs, with implications on the restrictive formulary adopted by the State of Louisiana in 1988.

This study is based on a statistical analysis of total Medicaid vendor payments for eleven types of services (Inpatient Hospital, General and Mental: Skilled Nursing Facilities; Intermediate Care, Mentally Retarded and "All Other"; Physician Services; Other Practitioner; Outpatient Hospital; Clinic Services; and Prescribed Drugs). Their analysis is based on a multivariate regression model that considers the simultaneous influence of many program characteristics on Medicaid costs. In essence, this analysis attempts to isolate the effect of a particular variable such as formulary status (i.e. restricted or unrestricted) on a variable such as vendor payments for prescribed drugs or inpatient hospitalization, while keeping other variables constant, such as total resident population, *per capita* income, unemployment rate, and number of persons in each state over the age of 65.

> States with high Medicaid expenditures are more likely to adopt restricted formularies. The study, however, incorrectly assumes that the reverse is true: restricted formularies result in high expenditures.

"Service Substitution Hypothesis"

Three variations of their basic model are presented that provide estimates of total Medicaid expenditures in a state whose formulary is restrictive in nature. These estimates show that Medicaid expenditures in states with restrictive formularies will be anywhere from 4.1 to 30.5 percent higher than they would if their formulary was open. The reason why this might occur, they hypothesize, is due to a "service substitution" effect. This service substitution hypothesis is based on a theoretical discussion in which the elimination of certain types of treatment (in this case the removal or restriction of certain drugs from a formulary) may cause physicians and patients to substitute other forms of therapy. Since if the initial therapy requested (e.g. the drug of choice) is not available, *any* substitute will therefore be of lesser quality and can result in higher Medicaid expenditures (e.g. higher doses for longer treatment periods of the substitute drug may be required).

The estimate of a 4.1 to 30.5 percent increase is questionable. Moore-Newman themselves state that the largest impact of 30.5 percent may be biased and misleading. Therefore, they believe an increase between 4.1 to 15.5 percent to be more realistic. These figures are further questioned in another PMA-sponsored study done at Vanderbilt University in Tennessee by F. Sloan. The purpose of the Tennessee study was to determine the fiscal impact of their restrictive Medicaid formulary on Medicaid expenditures based on Moore-Newman's methodology and findings. According to Sloan, only the model which predicts a 4.1 percent increase in Medicaid expenditures merits attention. However, Sloan acknowledges that this 4.1 percent increase failed to achieve a sufficiently high level of statistical significance. In other words, "the positive impact of a restrictive formulary estimated by the regression analysis could have occurred by chance". Even so, Sloan used Moore-Newman's flawed methodology and findings and, not surprisingly, came to the same conclusions as Moore-Newman.

> The study failed to establish a direct cause/effect relationship between restricted formularies and increased total Medicaid expenditures.

The Moore-Newman conclusions suggest that restricting the use of drugs will result in increased overall programs costs. However, the study failed to establish a direct cause/effect relationship between restricted formularies and increased total Medicaid expenditures. Furthermore, even if a cause/effect relationship were to be found in these restrictive-formulary states, these conclusions could not be extrapolated to the Medi-Cal pharmaceutical program because they assumed that all restrictive formularies eliminate entire coverage for certain drugs or drug-categories, in contrast to the Medi-Cal program's semi-restrictive nature (i.e. medically necessary drugs not on the Formulary are available via prior authorization).

Formulary Status: "Restricted vs. Unrestricted"

While the purpose of this study was to provide a method for isolating the effect of a particular independent variable (i.e. restrictive drug formularies) on various types of vendor payments, they have not adequately defined "restrictive drug formulary", thereby causing all subsequent data analysis and review to be biased and misleading.

To appreciate the seriousness of this error, one must closely examine the "formulary status" of the states included in the analysis. Of the 47 states included in this cross-sectional analysis, there are 21 states that claim to have a Medicaid drug formulary (19 with a restricted drug list and two which claim "no drug list, but certain categories are excluded from reimbursement"). The remaining 26 states claim to not have a drug formulary (only two states claim that "all legend drugs are reimbursed", the remaining 24 states have "no drug list, but certain categories are excluded from reimbursement).

The study fails to define "restricted" drug formulary, therefore, their analysis is questionable if not invalid.

The above description is included not to confuse the reader, but to show that "restricted formulary status" is not, according to the data, a simple yes/no condition as the authors define in their methodology where formulary status was defined as "restrictive" or "otherwise". Therefore, out of 47 states surveyed, only two can claim to have open or unrestrictive drug formularies. Since no raw data is presented in their paper, it is unclear which states or how many states they included in the "restricted" category. This is particularly confusing since one of the tables presented in the paper showed all the states were divided into the following three distinct categories: "Open Formulary", "Mild Restrictions" and "Restricted Formulary". One thing does become clear in this regard though, and that is each state has developed a unique Medicaid program within a broad framework of federal guidelines and that any gross comparisons between them specifically regarding formulary status are highly questionable.

State-specific Variations in Medicaid Programs

It is no surprise then that out of 50 states, there are in fact 51 (including the District of Columbia) different Medicaid programs providing a multitude of services for 51 diverse patient populations in 51 different economic markets.

There are even variations in Medicaid expenditures within states that make gross generalizations risky. For example, in San Francisco County, Medi-Cal pharmacy costs are 25 percent higher per recipient than Merced County. If we consider the differences between these two counties for Medi-Cal eligible patients, the figure is 52 percent higher for San Francisco County. This variation is seen in spite of the fact that eligibility criteria, benefit structure, reimbursement methodologies, etc., are the same in both counties. In this case, the major reason for the variations observed is due to differences in the patient population.

> There are variations in Medicaid expenditures that make gross generalizations risky. The Moore-Newman study fails to take these state-specific factors into consideration when performing the multivariate regression analysis.

The Moore-Newman study does not take any of these state-specific conditions into account. Even if they did, they could never control for all the possible variations that are in a constant state of change. It is not possible to ascertain the effect of restrictive drug formularies or total program expenditures by the methodology employed by Moore-Newman. Medicaid program characteristics vary so widely from state to state that virtually any multivariate regression analysis approach that does not take these state-specific factors into consideration must be considered flawed. Since we have no reliable way to make fair comparisons between state Medicaid programs using a multivariate regression methodology in regard to overall expenditures versus formulary status, we are left with making comparisons between states based on drug expenditures and total expenditures per Medicaid recipient. As seen in Table 1, California spends less per Medicaid recipient for drugs and spends less per recipient for over-all program expenditures than almost any other state.

As stated earlier, the Moore-Newman study results are based on a statistical analysis that uses the theoretical concept of health service substitution to explain their findings. In an attempt to add more support to this hypothesis, these authors further state that, "to the extent that new and higher quality drugs are excluded from a drug formulary, or at least delayed in entering the market under a restrictive formulary, the potential health care status of Medicaid patients will be diminished".

> Through their marketing strategies, the pharmaceutical industry would like the public to believe that all new drugs equal improvements in health care.

Many proponents of unrestrictive or open drug formulary systems have also postulated that formulary restrictions are unnecessary because only the most safe and efficacious drugs are approved for marketing by the FDA and only the most superior drugs are prescribed by physicians. This misconception is a major force behind the marketing strategies of the pharmaceutical industry, which would like nothing better than for the public to believe that a greater number of new drugs available equates to better health care.

IV. New Drug Products vs. Older Medications

Currently, the FDA approves the addition of new drugs to the American market solely on the basis of safety and efficacy. This approval is not contingent upon comparing the new drug that is seeking FDA approval with other drugs of similar therapeutic value. This is why a formulary system is so valuable. The FDA *does* however, classify each new drug according to its chemical type and therapeutic potential. Of the 348 new drugs introduced by the 25 largest U.S. drug manufacturers between 1981 and 1988, only 12, or 3 percent of the total were rated type "A", designating these as "Important therapeutic gains". Only 44, or 13 percent, were rated type "B" ("Modest therapeutic gains"). The remainder of these new drugs, 292 or 84 percent were rated Type "C" (providing "Little or no therapeutic gain"). Within the health care profession, drugs that provide little or no contribution to existing therapies are known as "me-too" drugs. As seen from the above example, the vast majority of new drugs coming to market in America fall into this "me-too" category. However, the prices established for these "me-too" products are anything but "little" or even "modest". It is well known, even in the public sector, that new drugs are priced higher and in most cases substantially higher than older medications.

> Of the 348 new drugs introduced by the 25 largest U.S. drug manufacturers between 1981 and 1988, the FDA rated only 3 percent as "Important therapeutic gain". Furthermore, 84 percent were rated as providing "Little or no therapeutic gain".

Unfortunately, few physicians have the opportunity to evaluate various drug products on a scientific or cost basis. The Medi-Cal formulary system provides an objective basis for prescribing decisions because DHS staff explore the scientific bases of competing claims and also consider drug alternatives that are not actively promoted but which represent good quality lower cost therapy. By screening out drugs of lesser quality, the Formulary serves as a useful guide to physicians for prescribing the most appropriate drug therapy.

New drug products have also been promoted to be safer alternatives than older medications. However, this increased safety has not always been realized in clinical practice. While the FDA approves drugs based in part on their safety profile, the data that is available to them for review does not always contain enough cumulative patient exposure time to pick up a relatively rare adverse reaction. It is not unusual for a new drug product to be removed from the American market a few months or years after its release due to an unusual but potentially lethal side effect. Examples of drugs that have met such a fate in the last few years are Selacryn, Zomax, Suprol, Oraflex, and Merital.

> FDA approval is not contingent upon comparing new drugs to existing drugs with similar values. An approved new drug is not necessarily an improvement over existing drugs in terms of efficacy, safety, or cost.

In April 1989, the FDA announced that two drugs widely used to treat heartbeat irregularities (Tambocor and Enkaid) were linked to an abnormally high rate of death in a control group study. In the last few years, the antibiotic Moxam has seen a decrease in utilization which most probably is due to episodes of bleeding. The above mentioned heart medications and antibiotic have not been removed from the market (nor do we want to imply that they should be), but they serve as examples of drugs that were found to have unexpected risks associated with their use that were not fully appreciated until after the drug became widely prescribed. In fact, the complete adverse reaction profile of virtually all drugs is not fully appreciated until a drug has been on the market for a number of years. One should not imply from this that we believe that older drugs are inherently safer than newer drugs but the fact remains that the more a medication is used, the better we know its adverse reaction profile. To reiterate, just because a new drug is available does not necessarily mean it will be an improvement over existing drugs in terms of efficacy or safety. This is contrary to what drug manufacturers are saying about their products, particularly when they are lobbying for an open drug formulary.

V. Consequences of an "Open" Medi-Cal Drug Formulary

As stated earlier, the purpose of a drug formulary is two-fold: to promote the appropriate use of drugs and to control the cost of drug therapy. Some of the consequences of an "open" Medi-Cal drug formulary become quite apparent when one reviews some specific cases of documented drug overutilization within the Medi-Cal Drug Program. Examples of such circumstances involves the overutilization of codeine products, the antianxiety drug Valium, and drugs used in the treatment of peptic ulcer disease. The overuse of these medicines is not just a local problem, but has been well established in the world-wide medical literature.

The purpose of the Medi-Cal Formulary is to promote the appropriate use of drugs and control costs. Documented cases of drug overutilization plague open formularies.

Overutilization

In September 1973, the Department entered into a pilot project contract with the manufacturer of Valium. Under the terms of the project, the manufacturer guaranteed that the State's expenditures for psychotherapeutic drugs (major tranquilizers, antidepressants, combinations thereof, and certain barbiturates) would be lessened if the restrictions on the use of Valium were removed. This however, was never realized. Due to dramatic increases (on the order of $3.5 million during the first year) in program costs, these restrictions had to be reinstituted.

In 1987, in an effort to decrease the overutilization of codeine products, the Department placed restrictions on their use. Since that time, the Department has realized very significant cost savings (currently between four and five million dollars per year) due to a decrease in the number of prescriptions for codeine-containing products. If the Department had been wrong in its assumption that such products were being prescribed beyond medical necessity, the utilization of the prior authorization system would have increased proportionately. This increase however, has not occurred.

Inappropriate Utilization

The medical literature has, for a number of years, provided many examples of the inappropriate use of antiulcer drugs. Commonly identified problems and associated factors include: use for unacceptable indications; long term use without diagnostic procedures being performed; incorrect dosage regimens, and most frequently, acute dosage levels prescribed for extended periods of time. The indiscriminate use and overutilization of these drugs is a problem experienced by health care administrators throughout the country in both inpatient and outpatient settings, and has been identified as a very significant problem occurring within the Medi-Cal population as well. Other state Medicaid programs have already instituted limitations on the use of antiulcer medications to control expenses and promote rational drug therapy.

In an effort to achieve more appropriate drug utilization and reduce the cost of treating peptic ulcer disease, the Department is currently proposing limitations on the use of the drugs that are commonly overprescribed in this area. Recently, the Medical Therapeutics and Drug Advisory Committee agreed with the Department's proposals and voted unanimously to recommend to the Director of Health Services to adopt such limitations.

Fiscal Implications

Removing all restrictions on drug usage by changing from a semi-restrictive formulary to an "open" formulary would result in dramatic increases in utilization of these and other drug products.

An open Medi-Cal Formulary would cost the California tax payer at least an additional $413 million.

Recently, DHS undertook the task of assigning a dollar value to the use of the Formulary in an unrestricted condition (Attachment 1). Specifically, a fiscal estimate was developed for the hypothetical change from a semi-restrictive Formulary to an unrestricted or open Formulary. The greatest impact will be on Medi-Cal expenditures for the ingredient cost of non-formulary drugs. The vast majority of these drugs fall into the "me-too" category that actually add little or no therapeutic advantage over existing drugs on the Formulary. The fiscal impact of such a change would increase annual program expenditures amounting to at least $413,953,000. This amount, however, does not take into account the increase in drug costs that would come from removing the restrictions on antianxiety drugs such as Valium, codeine products, and other drugs that have a high potential for abuse.

VI. CONCLUSION

The Medi-Cal Drug Formulary serves as a guide to physicians on appropriate drug therapy at a reasonable price. The Formulary is an effective means of minimizing payment for therapeutically disadvantageous and/or overpriced drugs while reducing the potential for overutilization of drugs. Its semi-restrictive nature provides the flexibility for coverage of unlisted drugs in medically necessary circumstances. Although the adequacy of the Formulary in meeting its objective has been questioned, such challenges are without merit. Therefore, the Formulary remains as an effective tool for controlling drug program expenditures without sacrificing quality of care and should remain in place.

The Medi-Cal Drug Formulary is an effective means of minimizing payment for therapeutically disadvantageous and/or overpriced drugs while reducing the potential for overutilization of drugs.

Table I
Relationship Between Total Health Care Costs Per Person and Drug Expenditures Per Person
A Comparison of State Medicaid Programs

	Total Cost Per Recipient	Drug Cost Per Recipient	Ranking: Total Cost Per Recipient	Ranking: Drug Cost Per Recipient
Mississippi	$1,133.00	$166.00	1	4
West Virginia	1,282.00	143.00	2	1
California	1,422.00	163.00	3	3
Alabama	1,454.00	213.00	4	20
Michigan	1,635.00	191.00	5	13
Kentucky	1,670.00	146.00	6	2
Montana	1,681.00	168.00	7	5
Hawaii	1,710.00	171.00	8	7
South Carolina	1,730.00	180.00	9	10
Oregon	1,755.00	233.00	10	28
Group Average	$1,547.20	$177.40		
Illinois	1,780.00	179.00	11	9
Louisiana	1,790.00	265.00	12	42
Missouri	1,810.00	194.00	13	14
Texas	1,832.00	168.00	14	6
Tennessee	1,855.00	260.00	15	40
Arkansas	1,904.00	206.00	16	18
Florida	1,944.00	261.00	17	41
Kansas	1,984.00	204.00	18	16
Georgia	2,058.00	291.00	19	47
New York	2,066.00	258.00	20	38
Group Average	$1,902.30	$228.60		
Pennsylvania	2,071.00	231.00	21	26
Iowa	2,073.00	223.00	22	25
Ohio	2,111.00	201.00	23	15
Washington	2,113.00	180.00	24	11
Utah	2,153.00	185.00	25	12
Nebraska	2,160.00	253.00	26	37
Vermont	2,209.00	242.00	27	32
Virginia	2,318.00	267.00	28	45
North Dakota	2,331.00	266.00	29	43
Oklahoma	2,377.00	215.00	30	22
Group Average	$2,191.60	$226.30		

	Total Cost Per Recipient	Drug Cost Per Recipient	Ranking: Total Cost Per Recipient	Ranking: Drug Cost Per Recipient
Wisconsin	2,442.00	279.00	31	46
Colorado	2,585.00	241.00	32	30
Nevada	2,595.00	217.00	33	23
Maryland	2,634.00	212.00	34	19
Idaho	2,656.00	243.00	35	33
Delaware	2,711.00	178.00	36	8
Maine	2,715.00	252.00	37	36
Alaska	2,884.00	213.00	38	21
South Dakota	3,000.00	249.00	39	34
New Mexico	3,223.00	233.00	40	27
Group Average	$2,744.50	$231.70		
Minnesota	3,296.00	236.00	41	29
Rhode Island	3,382.00	219.00	42	24
Indiana	3,445.00	363.00	43	49
North Carolina	3,625.00	250.00	44	35
Massachusetts	3,682.00	260.00	45	39
Dist. of Columbia	3,727.00	206.00	46	17
Connecticut	3,930.00	267.00	47	44
New Jersey	4,163.00	241.00	48	31
New Hampshire	5,004.00	324.00	49	48
Group Average	$3,806.00	$262.89		

ATTACHMENT 1

FISCAL ANALYSIS OF PROPOSED LEGISLATION FOR AN OPEN MEDI-CAL DRUG FORMULARY AND EXPANDED VITAMIN COVERAGE

Proposed legislation would extend Formulary coverage to all drugs approved by the Food Drug Administration (FDA), expand coverage for multi-vitamins. and initiate a $1 co-payment for all drug prescriptions (except for recipients under 21 years of age, long term care patients and for family planning prescriptions).

I. OPEN MEDI-CAL DRUG FORMULARY

Proposed legislation would eliminate the current Medi-Cal Drug Formulary process. and would allow for any drug approved by the FDA to be covered by Medi-Cal. The Medi-Cal Drug Formulary is a listing of drugs that are, with some exceptions. covered by the Medi-Cal program without prior authorization. Drugs are periodically added to or deleted from the Medi-Cal Drug Formulary based on petitions filed by drug manufacturers. The petitions are separately reviewed by Department staff and by the Medical Therapeutics and Drug Advisory Committee which recommend to the Director of Health Services as to which formulary changes should be approved. The Director makes the final decision after a public hearing has been held on each recommended petition. Drugs not on the Formulary are covered if treatment authorization requests (TARS) are approved.

The greatest impact will be on Medi-Cal expenditures for the ingredient cost of non-formulary drugs. This analysis projects a conservative impact because it assumes no increase in total Medi-Cal prescriptions, but rather a substitution in the usage of formulary-listed drugs by non-formulary drugs. Although the analysis assumes no increase in prescriptions. there are drug categories currently not available on the Formulary, or whose availability is very restricted : e.g., laxatives, anti-anxiety and anti-cholesterol drugs. These drugs would become readily available through an open formulary which would greatly increase costs by several millions of dollars. Another concern not addressed in this analysis is that quantity restrictions would be removed which could result in costly abuse of certain drugs; e.g., codeine and anti-anxiety drugs. Although these costs are impossible to quantify at this time, they would have a significant cost impact. There would also be some administrative savings in that pharmaceutical consultants now reviewing TARS and updating the Formulary would not be required.

Assumptions:

1. The top 200 drugs most often prescribed in the United States account for 52.1% of all drug prescriptions (Source: Pharmacy Times, April, 1989). Based on the utilization data presented in the article, non-formulary drugs were estimated to account for 40.0% of all drug prescriptions.

2. Assume that the nationwide utilization rate of 40.0% for non-formulary drugs would also be the substitution rate for these drugs in the Medi-Cal program given an open Formulary.

3. Total Medi-Cal drug prescriptions in FY 1988-89 were 29,317,000.

4. Non-Formulary Medi-Cal drug prescriptions approved through prior authorization were 297,308 in FY 1988-89.

5. The number of Formulary drug prescriptions to be substituted by Non-Formulary drugs as a result of an open formulary is computed as follows:

29,317,000	Total Medi-Cal Prescriptions
x .40	Non-Formulary Substitution Factor
11,726,800	Total Non-Formulary Prescriptions
- 297,300	Less Current Non-Formulary Approvals
11,429,500	Net Prescriptions being Substituted

6. Recent reports (July through Sept. 1989) on cost per prescription show an average prescription cost of $15.47 for Formulary drugs and $65.71 for Non-Formulary drugs.

7. The professional fee component per prescription is $4.05. The difference between the professional fee component and the cost per prescription is the drug ingredient cost. The higher ingredient cost of non-Formulary drugs is the component which will result in additional Medi-Cal costs as a result of implementing an open Formulary. The ingredient cost is calculated as follows:

	Formulary	Non-Formulary
Total	$15.47	$65.71
Professional Fee	- 4.05	- 4.05
Ingredient Cost	$11.42	$61.66

8. Part of the cost difference between Formulary and non-Formulary drugs is due to the fact that the quantity of drugs dispensed per prescription decreases when a drug is added to the Formulary. Based on data obtained for drugs before and after their addition to the formulary, the quantity of drugs dispensed is 31% higher before a drug is listed on the Formulary. This computes to a decrease of 24% in quantity prescribed when a drug is added to the Formulary.

$61.66	Cost per Non-Formulary Prescription
x (1-.24)	Quantity per Prescription Factor
$46.86	Adjusted Cost per Non-Formulary Prescription

9. The net cost per prescription to substitute a Formulary-listed drug with a non-Formulary drug is computed as follows:

$46.86	Cost per Non-Formulary Prescription
-11.42	Cost per Formulary Prescription
$35.44	Net Additional Cost per Prescription

10. Total cost to the Medi-Cal program of an open drug Formulary is:

11,429,500	Total Prescriptions being Substituted
x $35.44	Net Cost per Substituted Prescription
$405,061,500	Additional Medi-Cal Cost
$202,530,750	General Funds

11. The County Services Medical Program (CMSP), which covers county medically indigent adults and for whom the State reimburses at cost for, provides the same drug coverage as does the Medi-Cal program. Drug expenditures under this program is equivalent to .563% of Medi-Cal expenditures. Thus, the CMSP cost of an open Formulary is:

$405,061,500	Additional Medi-Cal Cost
x .00563	CMSP Factor
$ 2,280,500	Additional CMSP Cost
$ 2,280,500	General Fund Cost

II. EXPANSION OF VITAMIN COVERAGE

Proposed legislation would extend formulary coverage of multi-vitamins for children up to and including seven years of age, and geriatric vitamins for recipients sixty-five years of age and older.

Assumptions:

1. Currently, age group 0-5 years totals 558,324 in eligibles, and costs $2,691,000 annually for multi-vitamin therapy.

2. Adding coverage to age group 6-7, which total 183,396 in eligibles, would increase the pediatric population for multi-vitamins and costs by 33%.

$2,691,000	Current Multi-vitamin Cost for Ages 0-5
x .33	Factor for Addition of Ages 6-7
$ 888,000	Total Cost for Adding Coverage to Ages 6-7

3. Current eligible counts of age group 65 and over total 502,039.

4. Assume a $9.50 cost per prescription for 100 vitamins (a three month supply).

5. Assume 30% of the 65 and over age group will receive vitamin therapy.

502,039	Total Eligibles for Ages 65 and Over
x .30	% of Eligibles that will Receive Vitamins
x $ 9.50	Cost per Prescription
x 4	Number of Prescriptions per Year
$5,723,000	Total Cost for Adding Coverage to Ages 65+

$ 888,000	Total Cost for Adding Coverage to Ages 6-7
$5,723,000	Total Cost for Adding Coverage for Ages 65+
$6,611,000	Total Cost for Expanded Vitamin Coverage

III. COPAYMENT

Proposed legislation would require recipients to pay a $1 copayment for drug prescriptions, except for recipients under 21 years of age, long term care patients, or family planning or pregnancy related prescriptions. This copayment provision is marginally out of compliance with federal regulations which could jeopardize federal financial participation (FFP) for all drug expenditures. Current federal fund costs for drugs in jeopardy total $302,234,000. An open drug formulary would jeopardize an additional $205,836,250 in FFP for a total additional General Fund cost of $508,070,250.

SUMMARY OF FISCAL IMPACT:

	Total Funds	General Funds
Open Medi-Cal Formulary Costs	$405,061,500	$202,530,750
CMSP Costs	$ 2,280,500	$ 2,280,500
Expanded Vitamin Coverage	$ 6,611,000	$ 3,305,500
Total Additional Costs	$413,953,000	$208,116,750

Additional General Fund costs of $508,070,250 could occur annually if federal financial participation were to be lost for all Medi-Cal drug expenditures because the copayment provisions are not fully in compliance with federal Medicaid provisions. There are also significant but indeterminate costs which would occur through increased utilization of laxatives, anti-anxiety, and cholesterol-lowering drugs, and through loss of quantity restrictions for abusable drugs such as anti-anxiety drugs and codeine. In addition to these indeterminate costs, there are some administrative savings associated with the elimination of pharmaceutical consultants now reviewing TARS.

MEDI-CAL DRUG DISCOUNT PROGRAM

The Legislature finds and declares as follows:

(a) It is the intent of the Legislature to improve the health status of Medi-Cal beneficiaries at the least possible cost to the state.

(b) The Medi-Cal program is a large purchaser of drugs and should be entitled to employ usual business practices in securing drugs at discount prices.

(c) A customary business practice for drug manufacturers and distributors is to offer discount prices and rebates on drugs to their large volume purchasers, including other governmental agencies.

(d) In order to enable Medi-Cal to purchase drugs in the most cost-competitive manner and employ customary business practices, it is necessary to allow the State Department of Health Services to replace the Medi-Cal drug formulary with a list of contract drugs.

(e) It is the intent of the Legislature that the list of contract drugs contain a comprehensive mix of single-source and multiple-source drugs, sufficient to ensure beneficiary access to appropriate drug therapies. In addition, for persons with certain medical conditions, therapeutic equivalents are not interchangeable. Therefore, it is also the intent of the Legislature to ensure that within a therapeutic category, sufficient variety is available to accommodate medically necessary alternatives.

(f) The Legislature intends that Medi-Cal beneficiaries have available a comprehensive range of drug products and hereby directs the department to favorably review manufacturers' requests for drug product addition when those requests are accompanied with an acceptable best price contract offer, and the drug product otherwise meets the five criteria enumerated in subdivision (d) of Section 14105.39 of the Welfare and Institutions Code.

(g) It is the intent of the Legislature that the department improve the telephone access of providers to the current drug treatment authorization process. The department intends to meet this objective by expanding the resources available to the field offices, consistent with proposals included in the Budget Act of 1990. These additional resources are intended to increase availability of field office staff to providers. The Legislature further intends that the department respond to provider requests within 10 rings, or provide a secondary answering system to record provider calls. It is also intended that the department develop performance standards for responding to provider calls, consistent with the advances in technology the department is currently pursuing. In no event should these performance standards exceed eight working hours.

Section 14053.5 of the Welfare and Institutions Code is amended to read:

14053.5 For the purposes of the Medi-Cal Act, the terms "prescribed drug" and "prescription drug" shall not include any drug which, because of differing prices charged by the manufacturer on a discriminatory basis or discriminatory refusal to sell by the manufacturer, or both, is not available on the same terms and conditions to all providers of prescription services, or any drug which is found to be overpriced in comparison to another drug which has an equivalent therapeutic effect, unless the director determines that the drug is vital to the program and no acceptable substitute is available.

Before the director determines that any drug has an equivalent therapeutic effect in comparison to another drug, or is vital to the program and no acceptable substitute is available, he must have received a report to that effect from the Medi-Cal Contract Drug Advisory Committee.

Nothing is this section shall be construed to apply to quantity or other nondiscriminatory discounts available on the same terms and conditions to all providers of prescription services, to sales by competitive bidding to federal, state or local governmental agencies, or to sales to wholesalers so long as the manufacturer does not require or induce the wholesalers to make the drug available other than on the same terms and conditions to all providers of prescription services.

This section shall not be construed to deny reimbursement to hospitals for prescribed drugs furnished to inpatients or, unless the regulations provide to the contrary, to registered outpatients.

Section 14105.31 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.31. For purposes of the Medi-Cal contract drug list, the following definitions shall apply:

(a) "Single-source drug" means a drug which is produced and distributed under an original New Drug Application approved by the federal Food and Drug Administration. This shall include a drug marketed by the innovator manufacturer and any cross-licensed producers or distributors operating under the New Drug Application. A drug ceases to be a single-source drug when the same drug in the same dosage form and strength manufactured by another manufacturer is approved by the federal Food and Drug Administration under the provisions for an Abbreviated New Drug Application.

(b) "Best price" means the negotiated price, or the manufacturer's lowest price available to any class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities within the United States, which contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits, based upon the manufacturer's commonly used package sizes for the drug.

(c) "Equalization payment amount" means the amount negotiated between the manufacturer and the department for reimbursement by the manufacturer, as specified in the contract.

(d) "Manufacturer" means any person, partnership, corporation, or other institution or entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or in the packaging, repackaging, labeling, relabeling, and distribution of drugs.

(e) "Price escalator" means a mutually agreed upon price specified in the contract, to cover anticipated cost increases over the life of the contract.

(f) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.33 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.33. (a) The department may enter into contracts with manufacturers of single-source and multiple-source drugs, on a bid or nonbid basis, for drugs from each major therapeutic category, and shall maintain a list of those drugs for which contracts have been executed.

(b) Contracts executed pursuant to this section shall be for the manufacturer's best price, as defined in Section 14105.31, which shall be specified in the contract, and subject to agreed upon price escalators, as defined in that section. In no event shall the department require a manufacturer to provide a price lower than its lowest price to any class of trade, organization, or entity. The contracts shall provide for an equalization payment amount, as defined in Section 14105.31, to be remitted to the department quarterly. The department shall submit an invoice to each manufacturer for the equalization payment amount, based on utilization data from the department's prescription drug paid claims tapes.

(c) In order that Medi-Cal beneficiaries may have access to a comprehensive range of therapeutic agents, the department shall ensure that there is representation on the list of contract drugs in all major therapeutic categories. Except as provided in subdivision (a) of Section 14105.35, the department shall not be required to contract with all manufacturers who negotiate for a contract in a particular category. The department shall ensure that there is sufficient representation of single-source and multiple-source drugs, as appropriate, in each major therapeutic category.

(d) (1) The department shall select the therapeutic categories to be included on the list of contract drugs, and the order in which it seeks contracts for those categories. The department may establish different contracting schedules for single-source and multiple-source drugs within a given therapeutic category.

(2) The department shall make every attempt to complete the initial contracting process for each major therapeutic category by January 1, 1993.

(e) In order to achieve maximum cost savings, the Legislature declares that an expedited process for contracts under this section is necessary. Therefore, contracts entered into on a nonbid basis shall be exempt from Chapter 2 (commencing with Section 10290) of Part 2 of Division 2 of the Public Contract Code.

(f) Contracts executed pursuant to this section shall be confidential and shall be exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(g) The department shall provide individual notice to Medi-Cal beneficiaries at least 60 calendar days prior to the effective date of the deletion or suspension of any drug from the list of contract drugs. The notice shall include a description of the beneficiary's right to a fair hearing and shall encourage the beneficiary to consult a physician to determine if an appropriate substitute medication is available from Medi-Cal.

(h) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.35 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.35. (a) (1) On and after July 1, 1990, drugs included on the Medi-Cal drug formulary shall be included on the list of contract drugs until the department and the manufacturer have concluded contract negotiations or the department suspends the drug from the list of contract drugs pursuant to the provisions of this subdivision.

The department shall, in writing, invite any manufacturer with single-source drug products on the formulary as of July 1, 1990, to enter into negotiations relative to the retention of its drug or drugs. As to the issue of cost, the department shall accept the manufacturer's best price as sufficient for purposes of entering into a contract to retain the drug or drugs on the list of contract drugs.

If the department and a manufacturer enter into a contract for retention of a drug or drugs on the list of contract drugs, the drug or drugs shall be retained on the list of contract drugs for the effective term of the contract.

If a manufacturer refuses to enter into negotiations with the department pursuant to this subdivision, or if after 30 days of negotiation, the manufacturer has not agreed to execute a contract for a drug at the manufacturer's best price, the department may suspend from the list of contract drugs the manufacturer's single-source drug in question for a period of at least 180 days. The department shall lift the suspension upon execution of a contract for that drug. Consistent with the provisions of this section, the department shall delete the Medi-Cal drug formulary specified in paragraphs (b), (c), (d), and (e) of Section 59999 of Title 22 of the California Code of Regulations.

(2) On and after July 1, 1990, the director may retain a drug on the Medi-Cal list of contract drugs even if no contract is executed with a manufacturer, if the director determines that an essential need exists for that drug, and there are no other drugs currently on the formulary that meet that need.

(3) The director may delete a drug from the list of contract drugs if the director determines that the drug presents problems of safety or misuse. The director's decision as to safety shall be based upon published medical literature, and the director's decision as to misuse shall be based on published medical literature and the director's decision claims data supplied by the fiscal intermediary.

(b) Any reference to the Medi-Cal drug formulary by statute or regulation shall be construed as referring to the list of contract drugs.

(c) (1) Any drug in the process of being added to the formulary by contract agreement pursuant to Section 14105.3, executed prior to the effective date of this section, shall be added to the list of contract drugs.

(2) Contracts pursuant to Section 14105.3 executed prior to January 1, 1991, shall be considered to be contracts executed pursuant to Section 14105.33, and the department shall exempt the drugs included in these contracts from the initial therapeutic category review in which they would normally be considered.

(3) Nothing in this section shall be construed to require the department to discontinue negotiations into which it has entered with any manufacturer as of the effective date of this section. Contracts entered into as a result of these negotiations shall be exempt from the initial therapeutic category review in which they would normally be considered.

(d) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.37 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.37. (a) The department shall notify each manufacturer of drugs in therapeutic categories selected pursuant to Section 14105.33 of the provisions of Sections 14105.31 to 14105.42, inclusive.

(b) If, within 30 days of notification, a manufacturer does not enter into negotiations for a contract pursuant to those sections, the department may suspend or delete from the list of contract drugs, or refuse to consider for addition, drugs of that manufacturer in the selected therapeutic categories.

(c) If, after 120 days from the initial notification, a contract is not executed for a drug currently on the list of contract drugs, the department may suspend or delete the drug from the list of contract drugs.

(d) If, within 120 days from the initial notification, a contract is executed for a drug currently on the list of contract drugs, the department shall retain the drug on the list of contract drugs.

(e) If, within 120 days from the date of the initial notification, a contract is executed for a drug not currently on the list of contract drugs, the department shall add the drug to the list of contract drugs.

(f) The department shall terminate all negotiations 120 days after the initial notification.

(g) The department may suspend or delete any drug from the list of contract drugs at the expiration of the contract term or when the contract between the department and the manufacturer of that drug is terminated.

(h) Any drug suspended from the list of contract drugs pursuant to this section shall be subject to prior authorization, as if that drug were not on the list of contract drugs.

(i) Any drug suspended from the list of contract drugs pursuant to this section or Section 14105.35 for at least 12 months may be deleted from the list of contract drugs in accordance with the provisions of Section 14105.38.

(j) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.38 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.38. (a) (1) In the event the department determines a drug should be deleted from the list of contract drugs, the department shall conduct a public hearing, as provided in this section, to receive comment on the impact of removing the drug.

(2) (A) The department shall provide written notice 30 days prior to the hearing.

(B) The department shall send the notice required by this subdivision to the manufacturer of the drug proposed to be deleted and to organizations representing Medi-Cal beneficiaries.

(b) (1) The hearing panel shall consist of the Chief, Medi-Cal Drug Discount Program, who shall serve as chair, and the Medi-Cal Contract Drug Advisory Committee.

(2) The hearing shall be recorded and transcribed, and the transcript available for public review.

(3) Subsequent to hearing all public comment, and within 30 days of the hearing, each panel member shall submit a recommendation regarding deletion of the drug and the reason for the recommendation to the director.

(c) The director shall consider public comments provided at the hearing and the recommendations of each panel member in determining whether to delete the drug.

(d) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.39 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.39. (a) (1) A manufacturer of a new single-source drug may request inclusion of its drug on the list of contract drugs pursuant to Section 14105.33 provided all of the following conditions are met:

(A) The request is made within 12 months of approval for marketing by the federal Food and Drug Administration.

(B) The manufacturer agrees to negotiate a contract with the department to provide the drug at the manufacturer's best price.

(C) The manufacturer provides the department with necessary information, as specified by the department, in the request.

(D) The department had concluded contracting for the therapeutic category in which the drug is included prior to approval of the drug by the federal Food and Drug Administration.

(2) Within 90 days from receipt of the request, the department shall evaluate the request using the criteria identified in subdivision (d).

(b) Any petition for the addition to or deletion of a drug to the Medi-Cal drug formulary submitted prior to the effective date of this section, shall be deemed to be denied. A manufacturer who has submitted a petition deemed denied may request inclusion of that drug on the list of contract drugs provided all of the following conditions are met:

(1) The manufacturer agrees to negotiate for a contract with the department to provide the drug at the manufacturer's best price.

(2) The manufacturer provides the department with necessary information, as specified by the department, in the request.

(3) The manufacturer submits the request to the department prior to October 1, 1990.

(c) Any new drug designated as having an important therapeutic gain and approved for marketing by the federal Food and Drug Administration on or after the effective date of this section, shall immediately be included on the list of contract drugs for a period of three years provided that all of the following conditions are met:

(1) The manufacturer offers the department its best price.

(2) The drug is typically administered in an outpatient setting.

(3) The drug is prescribed only for the indications and usage specified in the federal Food and Drug Administration approved labeling.

(4) The drug is determined by the director to be safe, relative to other drugs in the same therapeutic category on the list of contract drugs.

(d) (1) To ensure that the health needs of Medi-Cal beneficiaries are met consistent with the intent of this chapter, the department shall, when evaluating a decision to execute a contract, and when evaluating drugs for retention on, addition to, or deletion from, the list of contract drugs, use all of the following criteria:

(A) The safety of the drug.

(B) The effectiveness of the drug.

(C) The essential need for the drug.

(D) The potential for misuse of the drug.

(E) The cost of the drug.

(2) The deficiency of a drug when measured by one of these criteria may be sufficient to support a decision that the drug should not be added or retained, or should be deleted from the list. However, the superiority of a drug under one criterion may be sufficient to warrant the addition or retention of the drug, notwithstanding a deficiency in another criterion.

(3) Notwithstanding paragraph (2) of this subdivision, when a manufacturer requests inclusion of a drug on the list of contract drugs pursuant to subdivision (a) or (b) of this section, as to the issue of cost, the department shall accept the manufacturer's best price as

sufficient for purposes of entering into negotiations for a contract to place the drug on the list of contract drugs if the following condition is met:

The course of therapy cost of the drug, as compared to the course of therapy cost of drugs within the same category currently on the list of contract drugs, would result in a savings to the drug portion of the Medi-Cal program if the drug were added to the list of contract drugs.

Nothing shall preclude the department from adding drugs to the list of contract drugs that do not meet the above-referenced condition.

(e) (1) A manufacturer of single-source drugs denied a contract pursuant to this section or Section 14105.33 or 14105.37, may file an appeal of that decision with the director within 30 calendar days of the department's written decision.

(2) Within 30 calendar days of the manufacturer's appeal, the director shall request a recommendation regarding the appeal from the Medi-Cal Contract Drug Advisory Committee. The committee shall provide its recommendation in writing, within 30 calendar days of the director's request.

(3) The director shall issue a final decision on the appeal within 30 calendar days of the recommendation.

(f) Changes made to the list of contract drugs, including those made pursuant to Section 14105.37, shall become effective no sooner than 30 days after publication of the changes in provider bulletins.

(g) Changes made to the list of contract drugs under this or any other section are exempt from the requirements of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code), and shall not be subject to the review and approval of the Office of Administrative Law.

(h) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.4 of the Welfare and Institutions Code is repealed.

Section 14105.4 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.4. (a) The director shall appoint a Medi-Cal Contract Drug Advisory Committee for the purpose of providing scientific and medical analysis on drugs contained on the list of contract drugs. The duties of the committee shall be as follows:

(1) To review drugs in the Medi-Cal list of contract drugs and make written recommendations to the director as to the addition of any drug or the deletion of any drug from the list. These recommendations shall be in accordance with subdivision (d) of Section 14105.39.

(2) To review and report in writing to the director as to the comparative therapeutic effect of drugs in accordance with Section 14053.5.

(3) To prepare a fair, impartial, end independent recommendation in writing, regarding appeals from manufacturers made pursuant to subdivision (e) of Section 14105.39.

(b) The committee shall consist of at least one representative from each of the following groups:

(1) Physicians.

(2) Pharmacists.

(3) Schools of pharmacy or pharmacologists.

(4) Medi-Cal beneficiaries.

(c) Members of the committee shall be reimbursed for necessary travel end other expenses incurred in the performance of official committee duties.

(d) In order to provide sufficient scientific information and analysis in the therapeutic categories under review, the director may replace a representative if required for specific expertise.

(e) The director shell notify the committee of the decisions made on the recommendations.

(f) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.4 is added to the Welfare and Institutions Code, to read:

14105.4. (a) The department shall schedule and conduct a public regulatory hearing to consider the addition of a drug to, or the deletion of a drug from, the Medi-Cal drug formulary five working days subsequent to the Medical Therapeutic and Drug Advisory Committee meeting which shall meet at least every four months. The public hearing may consist of written testimony only, and the hearing record shall be closed at the end of the public hearing.

(b) The department shall make available 45 days prior to the public hearing the department's estimate of any anticipated costs or savings to the state from adding a drug product to, or deleting a drug product from, the Medi-Cal drug formulary.

(c) Whenever the department accepts a completed petition to add a drug product to the Medi-Cal drug formulary and it is not processed pursuant to Section 14105.9, it shall be scheduled for review at the next regularly scheduled Medical Therapeutic and Drug Advisory Committee meeting and public regulatory hearing, unless the meeting and hearing are scheduled to occur within 120 days, in which case the drug product may be scheduled for the following hearing.

(d) The director shall issue a final decision regarding the drug product and shall submit any regulation adding a drug product to, or deleting a drug product from, the Medi-Cal drug formulary to the Office of Administrative Law, along with the completed rulemaking record, within seven months after the hearing prescribed in subdivision (a). This section shall not, however, be construed in a manner which results in the disapproval or invalidation of a regulation for failure to comply with the time frames prescribed in this subdivision and subdivisions (a) and (c).

(e) (1) Except as provided in paragraph (2), the criteria used by the department in deciding whether a drug product shall be added to or deleted from the formulary shall be limited to the criteria adopted as department regulations. The criteria shall be specific and unambiguous.

(2) Notwithstanding paragraph (1), either of the following may be submitted by the manufacturer in lieu of the Summary Basis of Approval prepared by the federal Food and Drug Administration for that drug:

(A) The federal Food and Drug Administration's approval or approvable letter for the drug and federal Food and Drug Administration's approved labeling.

(B) The federal Food and Drug Administration's medical officers' and pharmacologists' reviews and the federal Food and Drug Administration's approved labeling.

(f) Departmental requests for information from persons filing drug petitions to which this section applies shall be specific and unambiguous and shall be made solely for the purpose of addressing the criteria utilized in accordance with subdivision (e).

(g) All published studies received by the department pursuant to a drug petition prior to the close of the public regulatory hearing record shall be accepted and considered by the department.

(h) Whenever the director decides to reject a petition to add a drug product to, or delete a drug product from, the formulary, the director shall notify the petitioner directly and in writing indicating the reason and specifying the criteria utilized in reaching the decision.

(i) The department shall accept a petition for a drug that has been rejected by the director upon the submission of another complete petition containing substantial new information that addresses the reason or reasons for rejection stated by the director pursuant to subdivision (h). Any petition accepted pursuant to this subdivision shall be processed in accordance with subdivision (c), or Section 14105.9, whichever is applicable.

(j) This section shall become operative on January 1, 1993.

Section 14105.405 is added to the Welfare and Institutions Code, to read:

14105.405. (a) (1) A Medi-Cal beneficiary, within 90 days of receipt of the director's notice to beneficiaries pursuant to subdivision (g) of Section 14105.33, informing them of the decision to delete or suspend a drug from the list of contract drugs, may request a fair hearing pursuant to Chapter 7 (commencing with Section 10950) of Part 2.

(b) (2) A beneficiary filing a fair hearing request regarding the deletion or suspension of a drug from the formulary shall be granted a treatment authorization request for that drug until a final decision is adopted by the director. Should the beneficiary seek judicial review of the director's decision, a treatment authorization request shall be granted for that drug until a final decision is issued by the court.

(c) (1) A Medi-Cal beneficiary, within one year of the directors' decision pursuant to Section 10959, may file a petition with the superior court, under the provisions of Section 1094.5 of the Code of Civil Procedure, praying for a review of both the legal and factual basis for the director's decision.

(2) The director shall be the sole respondent in these proceedings.

(d) Any Medi-Cal beneficiary injured as a result of being denied a drug which is determined to be medically necessary may sue for injunctive or declaratory relief to review the director's decision to delete or suspend a drug from the list of contract drugs.

(e) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.406 is added to the Welfare and Institutions Code, to read:

14105.406. The director shall, in considering suspension or deletion of drugs from the list of contract drugs, ensure that the department has the ability to process drug treatment authorization requests (TARs) without substantial degradation of the level of service, including response time, to providers which was in effect July 1, 1990.

In considering suspension or deletion of drugs, the director shall seek the advice of the Chief of the Field Services Branch and the Medi-Cal Contract Drug Advisory Committee.

If the treatment authorization request reports provided in subdivision (b) of Section 14105.42 indicate a substantial degradation in the level of service, including response time, for processing TARs, the director shall within 60 days, hold a public hearing on the functioning of the TAR system.

Subsequent to the hearing, the director shall consult with at least two members of each group represented on the Medi-Cal Contract Drug Advisory Committee as provided in subdivision (b) of Section 14105.4 and take appropriate action to remedy the problem areas discussed in the report and in the public hearing.

Based upon the information gathered as a result of the reports and public hearing referred to above, and in consultation with the Medi-Cal Contract Drug Advisory Committee, the director may add drugs which previously had been suspended or deleted to the list of contract drugs.

Section 14105.41 of the Welfare and Institutions Code is repealed.

Section 14105.41 is added to the Welfare and Institutions Code, to read:

14105.41. (a) For the purpose of adding drugs to, or deleting drugs from, the Medi-Cal drug formulary as described in Section 14105.4, whether pursuant to a petition or by the department independent of a petition, all of the requirements of the Administrative Procedure Act contained in Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code shall be applicable except that the requirements of subdivision (a) of Section 11347.1 and subdivision (b) of Section 11346.7 of the Government Code shall be deemed to have been complied with if the department does all of the following:

(1) Upon receipt of a petition requesting the addition of a drug to, or the deletion of a drug from, the Medi-Cal drug formulary, the department shall notify the petitioner directly and in writing of the receipt of the petition and shall, within 30 days, either return the petition as incomplete or schedule the petition for public hearing, unless the public hearing is not required pursuant to Section 14105.9.

(2) Notifies each petitioner directly and in writing of its decision regarding the addition of a drug product to, or deletion of a drug product from, the formulary and shall state the reason or reasons for its decision and the specific regulatory criteria that are the basis of the department's decision.

(3) Prepares and submits to the Office of Administrative Law with the adopted regulation all of the following for each drug which the

department has decided to add to, or delete from, the Medi-Cal drug formulary:

(A) A brief summary of the comments submitted. For the purpose of this section, "comments" shall mean the major points raised in testimony which specifically address the regulatory criteria upon which the department is authorized, pursuant to subdivision (e) of Section 14105.4, to base a decision to add or delete a drug from the formulary.

(B) The recommendation of the Medical Therapeutic and Drug Advisory Committee.

(C) The decision of the department.

(D) A statement of the reason and the specific regulatory criteria that are the basis of the department's decision.

(b) Any additional information provided to the department during the posting of revisions to the proposed regulation shall be responded to by the department directly and in writing to the originator. That response shall notify the originator whether the additional information has resulted in a changed decision.

(c) For the purpose of review by the court, if any, and review and approval by the Office of Administrative Law of changes to the Medi-Cal drug formulary adopted by the department, each drug added to, or deleted from, the formulary shall be considered to be a separate regulation and shall be severable from all other additions or deletions of drugs contained in the rulemaking file.

(d) This section shall be applicable to any Medi-Cal drug formulary regulation package filed with the Office of Administrative Law after January 1, 1986.

(e) This section shall become operative on January 1, 1993.

Section 14105.41 of the Welfare and Institutions Code is repealed.

Section 14105.41 is added to the Welfare and Institutions Code, to read:

14105.41. (a) Moneys accruing to the department from contracts executed pursuant to Section 14105.33 shall be deposited in the Health Care Deposit Fund, and shall be subject to appropriation by the Legislature.

(b) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.42 of the Welfare and Institutions Code is repealed.

Section 14105.42 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.42. (a) The department shall report to the Legislature after the first three major therapeutic categories have been reviewed and contracts executed. The report shall include the estimated savings, number of manufacturers entering negotiations, number of contracts executed, number of drugs added and deleted, and impact on Medi-Cal beneficiaries and providers.

(b) The department shall provide the following data to the Legislature and to the Auditor General by January 1, 1991, and every six months thereafter:

(1) The number of drug treatment authorization request (TAR) received by facsimile, by secondary answering system and in person for each therapeutic category.

(2) The number of drug TARS requested, approved, denied, and returned.

(3) The length of time between the TAR request and the decision, specified by type of communication such as telephone or facsimile if available.

(4) For denied TARS, the number of fair hearings requested, approved, denied and pending.

(5) The numbers of providers who were unable to submit a request or made multiple attempts because of faulty or unavailable lines of communication, if available.

(6) The numbers of complaints made by beneficiaries and providers relating to difficulty or inability to obtain a TAR response.

(7) The status of the enhancements to the TAR process specified in the section.

(8) The number of calls on the TAR line which are not getting through.

(c) The Auditor General shall prepare a report by February 1, 1991, and every 6 months thereafter providing a summary and analysis of the data specified in subdivision (b), a comparative analysis of changes in the TAR process using June 1, 1990, as a base. The analysis shall include a measure of increased or decreased ability to contact the department and receive a response in a shorter or greater period of time.

(d) The department shall report to the Legislature, through the annual budget process, on the cost-effectiveness of contracts executed pursuant to Section 14105.33.

(e) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14105.42 is added to the Welfare and Institutions Code, to read:

14105.42. The provisions of Sections 14105.4 to 14105.41, inclusive, and Section 14105.65 shall not preclude the department from taking emergency regulatory action as it deems appropriate.

This section shall become operative on January 1, 1993.

Section 14105.43 of the Welfare and Institutions Code is amended to read:

14105.43. (a) Notwithstanding other provisions of this chapter, any drug which is approved by the United States Food and Drug Administration for use in the treatment of acquired immune deficiency syndrome (AIDS) or an AIDS-related condition shall be deemed to be approved for addition to the Medi-Cal list of contract drugs only for the purpose of treating AIDS or an AIDS-related condition, for the period prior to the completion of the procedures established pursuant to Section 14105.33.

(b) Any drug deemed to be approved pursuant to subdivision (a) shall be immediately added to the Medi-Cal list of contract drugs, and shall be exempt from the contract requirements of Section 14105.33.

(c) If it is determined pursuant to subdivision (d) of Section 14105.39 that a drug to which subdivision (a) applies should not be placed on the Medi-Cal list of contract drugs, that drug shall no longer be deemed to be approved for addition to the list of contract drugs pursuant to subdivision (a).

Section 14105.45 of the Welfare and Institutions Code, as added by Assembly Bill 3573 of the 1989-90 Regular Session, is amended to read:

14105.45. The department shall establish a list of Maximum Allowable Ingredient Costs (MAIC) for drugs, which shall be published in provider bulletins. On the effective date of this section, MAICS listed in Title 22 of the California Code of Regulations shall be included in the list of MAICS. MAICs shall no longer be listed in regulations. The department shall repeal Section 51513.3 of Title 22 of the California Code of Regulations.

(b) The department shall establish additional MAICS in accordance with all of the following:

(1) The department shall base an MAIC on a reference drug brand which is therapeutically equivalent to the innovator brand, and which is manufactured by a company with production capability to meet the statewide needs of the Medi-Cal program for that drug.

(2) The decision regarding therepeutic equivalency shall be besed on the federal Food and Drug Administretion determinetions. For antecid drugs, therapeutic equivalency shall be determined by the department based on review of in vitro scientific data.

(3) The department shall request information from drug manufecturers regarding the availability of their products throughout the state to outpatient pharmacies through the usual and customary distribution channels in sufficient quantities to meet the needs of the Medi-Cal program.

(4) The department shall notify Medi-Cal providers et least 30 days prior to the effective date of an MAIC.

(c) Notwithstanding the provisions of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, actions under this section shall not be subject to the Administrative Procedure Act, or to the review and approval of the Office of Administrative Law.

Section 14105.7 of the Welfare and Institutions Code is amended to read:

14105.7. (a) In order to fairly reimburse pharmacies for the furnishing of prescription drugs to Medi-Cal beneficiaries, the director shall update allowable drug product prices no less often than every 30 days. The update shall include any prior change in drug product price of which the director has received notice. Notice to the director shall include, but not be limited to, publication of the price change in the supplier's catalog or supplement or in nationally distributed drug price reference guides.

(b) No regulation reducing allowable drug product cost reimbursement or removing a drug from the Medi-Cel list of contract drugs shall be operative until at least 30 days after eligible pharmacies have bean mailed a notice of the reimbursement limitation by the department or the fiscal intermediary.

(c) The director shall limit the rate of payment for the professional fee portion of prescription services rendered under this chapter pursuant to Section 4229.5 of the Business and Professions Code or Section 11201 of the Health and Safety Code and the professional fee portion of prescription services rendered as a refill immediately subsequent to such prescription to ensure that the total professional fee paid for the two services does not exceed the professional fee paid for the same prescription refill when provided as a routine service.

Section 14105.91 of the Welfare and Institutions Code is repealed.

Section 14105.91 is added to the Welfare and Institutions Code, to read:

14105.91. The department may add a drug to the formulary which is a different dosage form, or strength of a drug product which is listed in the formulary without review by the Medical Therapeutics and Drug Advisory Committee and the addition shall be deemed to comply with the requirements of the California Administrative Procedures Act.

This section shall become operative on January 1, 1993.

Section 14105.915 is added to the Welfare and Institutions, to read:

14105.915. The department may remove any drug from the formulary at the expiration of the contract term or when the contract between the department and the manufacturer of that drug is terminated.

This section shall become operative on January 1, 1993.

Section 14105.916 is added to the Welfare and Institutions Code, to read:

14105.916. Notwithstanding any other provision of law, on and after January 1, 1993, drugs on the Medi-Cal list of contract drugs shall become the Medi-Cal drug formulary.

Section 14105.92 of the Welfare and Institutions Code is amended to read:

14105.92. (a) Notwithstanding any other provision of law, pentoxifylline tablets shall, no later than July 1, 1990, be added to the Medi-Cal list of contract drugs for treatment of persons diagnosed as having both diabetes and intermittent claudication.

(b) For indications other than intermittent claudication, pentoxifylline may only be available upon approval of a prior authorization request submitted by a qualified provider, unless other indications are authorized pursuant to regulations adopted by the department.

(c) Pentoxifylline tablets shall be exempt from the contract requirements of Section 14105.33.

(d) This section shall remain in effect only until January 1, 1993, and as of that date is repealed, unless a later enacted statute, which is enacted before January 1, 1993, deletes or extends that date.

Section 14132 of the Welfare and Institutions Code is amended to read:

(a) through (c) unchanged.

(d) Purchase of prescribed drugs is covered subject to the Medi-Cal list of contract drugs and utilization controls.

(e) through (z) unchanged.

Section 14132d of the Welfare and Institutions Code, as added by Assembly Bill 4104 of the 1989-90 Regular Session, is amended to read:

14132d. Any purchase of prescribed drugs is covered under this chapter subject to the Medi-Cal list of contract drugs and utilization controls.

Section 14133.2 of the Welfare and Institutions Code is amended to read:

14133.2. The director shall include in the Medi-Cal list of contract drugs any drug approved for the treatment of cancer by the Federal Food and Drug Administration. These drugs shall be exempt from the contract requirements of Section 14105.33.

Article 5.5 (commencing with Section 14180) of Chapter 7 of Part 3 of Division 9 of the Welfare and Institutions Code is repealed.

The State Department of Health Services may adopt emergency regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, to implement Sections 13 to 28, inclusive, and Sections 30 to 33, inclusive, of this act. The adoption of those regulations shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, or safety. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, emergency regulations adopted by the department in order to implement Sections 13 to 28, inclusive, and Sections 30 to 33, inclusive, of this act shall not be subject to the review and approval of the Office of Administrative Law. These regulations shall become effective immediately upon filing with the Secretary of State.

Section 34 of Assembly Bill 3573 of the 1989-90 Regular Session is amended to read:

Sec. 34. (a) Except as provided in subdivision (b), the department shall adopt emergency regulations pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code within 120 days of the enactment of this act to implement Section 33 of this act. The adoption of regulations pursuant to this section in order to implement Section 33 of this act shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, or safety. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, emergency regulations adopted pursuant to this section within 120 days of the enactment of this act shall not be subject to the review and approval of the Office of Administrative Law. The regulations shall become effective immediately upon filing with the Secretary of State. The regulations shall not remain in effect more than 120 days unless the adopting agency complies with all of the provisions of Chapter 3.5 (commencing with Section 11340) as required by subdivision (e) of Section 11346.1 of the Government Code.

(b) The dispensing or markup fee, which is a factor in reimbursement for incontinence medical supplies as described in Section 14125 of the Welfare and Institutions Code, shall not be changed or adopted pursuant to the authorization to adopt emergency regulations set forth in subdivision (a).

Mr. **Waxman.** Thank you very much, Mr. Parks.

Why don't we go straight down the line. Mr. Mossinghoff.

STATEMENT OF GERALD J. MOSSINGHOFF

Mr. **Mossinghoff.** Thank you, Mr. Chairman.

In line with your opening remarks, I will not address those parts of my statement that were directed towards S. 2605 or the OMB proposal for therapeutic substitution.

I would like to make, initially at least, four points regarding prescription drugs in the United States. First, single source or patented drugs in the Medicaid program of the estimated $5 billion cost of the Medicaid program in fiscal year 1991, of that $5 billion, less than $1.5 billion, or only $1.5 billion is expended on single-source drugs, less than the multiple source drugs, $1.9 billion.

Second, our recent analysis of the largest Medicaid program, California's Med-Cal program, shows that over 60 percent of the increase in drug expenditures from 1984 to 1989 was due to increased utilization, not the cost of prescriptions.

Increased utilization has resulted from expansions in Medicaid eligibility and an increased number of prescriptions per Medicaid patient. Increased use of prescription drugs by Medicaid patients is consistent with the general shift of patients from inpatient to lower cost outpatient care, and the widespread recognition of the cost-effectiveness of prescription drugs.

Three, although the overall cost of medical care in the United States has represented an everincreasing share of GNP, prescription drugs have claimed less than 1 percent of GNP for the past 25 years. The percentage was 0.84 percent in 1965 and 0.86 percent in 1988, the last year for which Health Care Financing Administration data are available.

While claiming a small and remarkably constant percentage of the U.S. GNP, America's research-based pharmaceutical industry has established itself as a world leader in high technology, one that has consistently enjoyed a positive trade balance.

Four, over the past 6 years, PMA member firms have contributed to substantial Medicaid program savings as a result of the streamlined generic approval process of the Drug Price Competition and Patent Term Restoration Act of 1984. More than 1,800 abbreviated new drug applications have been approved by the Food and Drug Administration since the enactment of that law, providing generic competition to a significant portion of the brand-name market.

An independent drug analyst recently noted in Investors Daily that brand-name drugs with annual sales of $10 billion are scheduled to go off patent between 1991 and 1995.

Four leading research-based pharmaceutical companies—Merck, Glaxo, Pfizer and Upjohn—have each proposed ways to save money in the Medicaid program. You will hear from officials of Merck and Glaxo this morning. As I have noted, Pfizer and Upjohn have provided to me the descriptions of their respective proposals, and these are attached to my statement.

Several other PMA member companies have endorsed one or more of these four proposals. Perhaps more important, more than a dozen PMA companies are now reported to be negotiating discounts and rebates with Medicaid officials. These companies represent slightly more than half of the Medicaid single-source drug market. Forty-two States are involved in these negotiations; they represent more than 90 percent of the total Medicaid drug market.

A hallmark of the negotiations now being undertaken in the States is that, in return for discounts or rebates, States are providing Medicaid patients greater access to new innovative prescription drugs. That is an overarching objective of virtually all of the organizations that have joined together in the coalition to oppose S. 2605 or the OMB proposal or both.

Any Federal legislation which could impede the current trend in the States would be counterproductive to better, more cost-effective health care in the Medicaid program.

Turning to Congressman Wyden's bill are four statements I would like to make.

One is, statements regarding H.R. 5589 and S. 3029 could lead to an interpretation that a drug would be automatically available to patients in the Medicaid program if the manufacturer provided a rebate.

A reading of the bills themselves, however, indicates that this is not the case. Even if the manufacturer provided a rebate, States could still subject any drug to a prior approval system.

In an attempt to simplify the current unsatisfactory prior approval systems, the bills would provide for an immediate telephonic response to a request by a doctor for approval. The bills do not, however, provide any criteria for prior approval or disapproval, or provide an appeal procedure if the doctor is overruled.

By requiring prior approval for some drugs and not others, this provision would permit a de facto restrictive formulary even though all manufacturers would be required to provide a rebate. All of this is in sharp contrast to what is happening in the States now in negotiations. States are providing automatic access to new innovative drugs in return for discounts or rebates.

Second, H.R. 5589 and S. 3029 are inherently unfair. Their economic impact would vary widely from company to company. The bills, for example, would index a "best price" given to the Department of Veterans' Affairs in order to calculate a rebate in the Medicaid program.

Many of our companies are reported as giving deep discounts to the DVA, a practice that for some goes back to World War II. Those companies would be hit hardest under the bills. Penalizing a company for having a practice of giving a deep discount to the Department of Veterans' Affairs, a practice which I would submit is not reprehensible, is not sound public policy.

[Testimony resumes on p. 625.]

[The prepared statement of Mr. Mossinghoff follows:]

Statement

Pharmaceutical
Manufacturers
Association

GERALD J. MOSSINGHOFF
PRESIDENT
PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

SEPTEMBER 14, 1990

Mr. Chairman and Members of the Subcommittee:

I appreciate this opportunity to appear before the Subcommittee on Health and the Environment to discuss with you the very important subject of Medicaid prescription-drug purchasing.

In my prepared statement I will discuss Senator Pryor's proposed legislation, S.2605, and the reasons why PMA and dozens of patient groups, voluntary health organizations, medical societies, and state and Federal legislators oppose its enactment. I will also outline the reasons underlying the strong opposition to an OMB Medicaid proposal for therapeutic substitution that was sent to the Budget Summit negotiators on June 20. Several of our member companies are now negotiating rebates and discounts in the states, and four PMA companies -- Merck, Glaxo, Pfizer, and Upjohn -- have made proposals to achieve savings in the Medicaid prescription-drug program. Merck and Glaxo are represented here today to testify. At their request I have attached to my statement summaries of the proposals of Pfizer and Upjohn (Attachments 1 and 2, respectively) which they provided to me. Finally, I will comment on H.R.5589 and S.3029, which were introduced Wednesday.

Also attached to my statement (Attachment 3) is a pamphlet published by PMA on "Medicines in Medicaid," which provides basic data on the research-based pharmaceutical industry's contribution to Medicaid patients. In the interest of time, I will only make four observations regarding prescription drugs in the United States:

(1) Single-source or patented drugs amount to only $1.5

billion of the estimated $5 billion cost of Medicaid prescription drug coverage in fiscal year 1991, less than multiple-source drugs ($1.9 billion) and pharmacy markups and dispensing fees ($1.6 billion).

(2) Our recent analysis of the largest Medicaid program, California's Medi-Cal program, shows that over 60% of the increase in drug expenditures from 1984 to 1989 was due to increased utilization, not the cost of prescriptions. Increased utilization has resulted from expansions in Medicaid eligibility and an increased number of prescriptions per Medicaid patient. Increased use of prescription drugs by Medicaid patients is consistent with the general shift of patients from in-patient to lower-cost out-patient care, and the wide-spread recognition of the cost-effectiveness of prescription drugs.

(3) Although the overall cost of medical care in the United States has represented an ever-increasing share of GNP, prescription drugs have claimed less than 1% of GNP for the past 25 years. The percentage was 0.84% in 1965 and 0.86% in 1988, the last year for which Health Care Financing Administration data are available. While claiming a small and remarkably constant percentage of the U.S. GNP, America's research-based pharmaceutical industry has established itself as a world leader in high technology, one that has consistently enjoyed a positive trade balance.

(4) Over the past six years, PMA member firms have contributed to substantial Medicaid program savings as a result of the streamlined generic approval process of the Drug Price Competition and Patent Term Restoration Act of 1984. More than 1800 Abbreviated New Drug Applications have been approved by the Food and Drug Administration since the enactment of that law, providing generic competition to a significant portion of the brand-name market. The brand-name products typically lose half of their market to generic competition within two years after patent expiration. Savings as a result of increased generic competition will continue. An independent drug analyst recently noted in Investors Daily that brand-name drugs with annual sales of $10 billion are scheduled to go off patent between 1991 and 1995.

S.2605

Since the introduction of S.2605 on May 10, 1990, dozens of leading patient groups, voluntary health organizations, medical societies and key policy makers have voiced vigorous opposition to its enactment. Lists of those who oppose enactment of S.2605 are attached to my statement as Attachments 4 and 5. Those listed in Attachment 5 have stated their opposition both to S.2605 and to the OMB proposal.

The statements, of course, speak for themselves, and although they are voluminous, I respectfully request that they be included in the record of this hearing. Given the stature of the many organizations and individuals expressing strong opinions and the fact that they represent millions of Americans, I would submit that their views should be considered by the Subcommittee in its deliberations.

Essentially, the opposition to S.2605 is based on the following reasons:

o An inherent flaw in S.2605 is in its underlying premise that entirely different drugs having unique chemical structures are somehow therapeutically interchangeable among patients who have vastly different medical profiles.

o A result of S.2605 -- indeed its intended result -- is that drug therapy in Medicaid would be chosen by low-bid, not by the medical judgment of the patient's physician. The bill would thus result in second-class medical care for Medicaid recipients.

o The cumbersome pharmacist-to-physician call-back system of S.2605 would undoubtedly lead to two lines at the pharmacist's counter: one where prescriptions would be filled promptly and a second Medicaid line of persons waiting for the pharmacist to exercise "diligent efforts" to reach the physician to get permission to substitute a low-bid drug for the one originally prescribed.

o The "three-day-supply" provision of S.2605 would force Medicaid patients to return to a pharmacy in three days if, as would happen in hundreds of thousands of cases, the pharmacist could not reach the physician after "diligent efforts." Considering the fact that only an estimated 10% of Medicaid patients have independent means of transportation, this provision would be extremely burdensome, particularly in rural areas.

o The significant costs of administration involved in S.2605 -- which according to the Congressional Budget Office would involve an additional 1,000 Federal officials and 1,000 state employees -- would more than offset any possible "savings" from substituting low-bid drugs.

S.2605 is an extremely complex bill and to discuss it thoroughly would require far more than the time allotted to me this morning. I have attached to my statement the following documents:

Attachment 6 -- A legal opinion from Lloyd N. Cutler, Esq., stating his views that the closed-door process of selecting "therapeutic alternatives," which would be required by S.2605, would be unconstitutional;

Attachment 7 -- A letter from the law firm of Sidley & Austin commenting on the increased professional liability exposure for physicians that S.2605 would cause, and

Attachment 8 -- A May 22, 1990 "White Paper" setting forth PMA's detailed comments on S.2605.

The Office of Management and Budget's June 20 Proposal

As part of the Budget Summit efforts, the Office of Management and Budget proposed a scheme for savings in the Medicaid program that went well beyond S.2605. Instead of requiring the pharmacist-to-physician call-back of S.2605 before the low-bid drug could be substituted, the OMB proposal would require naked therapeutic substitution. Unless the physician wrote that the prescribed drug was "medically necessary," the pharmacist would be required to dispense a low-bid drug consisting of an entirely different active chemical from the one prescribed, without the knowledge of the physician or the patient. Recognizing the real dangers inherent in its proposal, OMB would hold pharmacists, but not physicians, harmless from resulting injury or death to the patient. As pointed out in a joint statement by the American College of Cardiology and the American Heart Association, therapeutic substitution represents "a real and present danger to individual patients."

To my knowledge no one has supported the OMB proposal. A list of those who issued statements vigorously opposing it is attached to my statement (Attachment 9). Again, since these statements speak for themselves, I respectfully request that the statements themselves be made a part of the hearing record.

Company Proposals

Four leading research-based pharmaceutical companies -- Merck, Glaxo, Pfizer, and Upjohn -- have each proposed ways to save money in the Medicaid program. You will hear from officials of Merck and Glaxo this morning. As I have noted, Pfizer and Upjohn have provided to me the descriptions of their respective proposals, and these are attached to my statement.

Several other PMA member companies have endorsed one or more of these four proposals. Perhaps more important, more than a dozen PMA companies are now reported to be negotiating discounts and rebates with Medicaid officials. These companies represent slightly more than half of the Medicaid single-source drug market. Forty-two states are involved in these negotiations; they represent more than 90% of the total Medicaid drug market.

A hallmark of the negotiations now being undertaken in the states is that, in return for discounts or rebates, states are providing Medicaid patients greater access to new innovative prescription drugs. That is an overarching objective of virtually all of the organizations that have joined together in the coalition to oppose S.2605 or the OMB proposal or both. Any Federal legislation which could impede the current trend in the states would be counterproductive to better, more cost-effective health care in the Medicaid program and should not be enacted.

H.R.5589/S.3029

This past Wednesday Congressmen Wyden and Cooper and Senator Pryor introduced legislation (H.R.5589 and S.3029) to require rebates from drug manufacturers whose products are prescribed in the Medicaid program. In his introductory remarks, Senator Pryor made clear that S.3029 is not a substitute for S.2605, which he is still advocating. Each of the bills is quite complex, and my comments at this hearing are based on our initial impressions. Nevertheless, I would like to make several points on the bills.

o Statements regarding H.R.5589 and S.3029 could lead to an interpretation that a drug would be automatically available to patients in the Medicaid program if the manufacturer provided a rebate. A reading of the bills themselves, however, indicates that this is not the case. Even if the manufacturer provided a rebate, states could still subject any drug to a prior-approval system. In an attempt to simplify the current unsatisfactory prior-approval systems, the bills would provide for an immediate telephonic response to a request by a doctor for prior approval. The bills do not, however, provide any criteria for prior approval or disapproval, or provide an appeal procedure if the doctor is overruled. By requiring prior approval for some drugs and not others, this provision would permit a de facto restrictive formulary even though all manufacturers would be required to provide a rebate. All of this is in sharp contrast to what is happening in the states now in negotiations for discounts and rebates in the Medicaid program; states are providing automatic access to new innovative drugs in return for discounts or rebates.

o H.R.5589 and S.3029 are inherently unfair. Their economic impact would vary widely from company to company. The bills, for example, would index a "best price" given to the Department of Veterans Affairs in order to calculate a rebate in the Medicaid program. Many of our companies are reported as giving deep discounts to the DVA, a practice that for some goes back to World War II. Those companies would be hit hardest under the bills. Penalizing a company for having a practice of giving a deep discount to the Department of Veterans Affairs -- a practice which I would submit is not reprehensible -- is not sound public policy.

o The idea of price controls is inimical to this country's free-market economy. Price controls are totally unreasonable in the absence of controls over a manufacturer's cost of doing business, including wages, energy, transportation, etc. A quintessential feature of recent worldwide developments is that free-market forces serve society far better than centrally planned and administered controls.

o A provision of S.3029 [Section 1927(f)(3)] seems to be punitive in nature. It requires that if a generic copy of a drug may be dispensed under state law, no payment for the innovator's drug may be made even if it is less expensive to the program than the generic. The thrust of both bills in the multisource arena is discriminatory. Companies doing exactly the same thing -- namely, manufacturing and selling a multisource drug -- are treated very differently depending on whether they are an originator or a copier, with the originator being greatly disadvantaged. This raises fundamental issues of fairness and serious constitutional questions.

o There is no justification for the provisions of S.3029 to take money in the form of rebates from manufacturers in order to pay a portion to major chain stores, supermarkets and large mail-order houses, among others. That may be good politics; it is not sound public policy and does nothing for the Medicaid program.

Mr. Chairman, there are many other aspects of H.R.5589 and S.3029 which I know PMA will want to comment on. Given the short time we have had to analyze the bills, I wanted to highlight our most serious initial concerns. Given the keen interest of the Committee on Energy and Commerce in America's competitiveness, I would hope that the Committee will give serious consideration to the inevitable effects enactment of these bills would have on the very beneficial and internationally competitive research-based pharmaceutical industry.

Mr. Chairman, that concludes my prepared statement. I would be pleased to respond to any questions you and the Subcommittee may have.

ATTACHMENT 1

9/6/90

Outline of Pfizer Medicaid Proposal

Because many state Medicaid programs are experiencing financial difficulties, they have restricted patients' access to various types of care, including prescription drugs. Pfizer has proposed federal legislation to address the issues of Medicaid patients' access to, and Medicaid's cost of, prescription drugs.

Prescription drugs are the most appropriate and cost-effective treatment for many medical conditions. Pfizer's proposal, which assures that Medicaid programs will receive the best price available in the U.S. marketplace, will enable the programs to realize substantial savings. By opening Medicaid formularies, the proposal will lead to improved treatment for Medicaid patients while permitting physicians to choose cost-effective treatment options. Medicaid patients will have access to all necessary prescription drugs at the lowest market price.

The key elements of Pfizer's proposal are:

1. Best Market Price/Quarterly Medicaid Discount Payments - Manufacturers would be required to make quarterly Medicaid Discount Payments to Medicaid programs in amounts that assure that the programs receive the best market price available in the U.S.

2. Open Access - Effective October 1, 1992, States that reimburse prescription drugs would be required to reimburse all sole source drugs with no requirement for prior authorization.

3. No Federal Formulary - The federal government would not be permitted to establish a Medicaid formulary.

4. Multiple Source Drugs - All sectors of the marketplace for prescription drugs should contribute to Medicaid savings. Possible options for multiple source drugs include: codify the current HCFA regulations (150% of the lowest priced drug product); use the same "best price" formula as proposed for sole-source drugs; or, competitive bidding.

5. Transition Provisions - In any state that provides open access, manufacturers would make payments equal to one-third of the Medicaid Discount Payment for the period from enactment to October 1, 1991, and two-thirds of the Medicaid Discount Payment for the period from October 1, 1991 to October 1, 1992.

ATTACHMENT 2

The Upjohn Company

WEIGHTED MEDICAID Rx REBATE

A formula offering 75 cents claims processing and 3% of the total prescription cost rebate would provide a weighted prescription rebate. Total prescription price provides a simple and convenient anchor on which to calculate future rebates and includes increases in pharmacist reimbursement.

Advantages of the weighted prescription rebate formula are:

- on average the rebate per prescription would range from less than $1.00 to $2.48 per supplier with the major research pharmaceutical manufacturers contributing larger rebates,
- administrative simplicity,
- rebate calculations are possible from Medicaid Management Information System (MMIS) data, and
- total rebate savings should exceed $300 million, assuming 220 - 250 million Medicaid prescriptions at an average of $1.30 - $1.40 per prescription.

ATTACHMENT 3

Pharmaceutical Manufacturers Association

Medicines in Medicaid:
Cost-Effective Health Care for America's Poor

Pharmaceutical Innovation: The Key to Medicaid Cost-Effectiveness

Prescription drugs play a key role in the success of Medicaid, a program which provides health care to the nation's poorest patients.

Drugs save lives and extend life expectancy. Equally important, drugs are among the most cost-effective medical technologies, with only about a nickel of every U.S. health care dollar being spent on outpatient prescription drugs. Today's new medicines, in fact, help to restrain escalating health care costs by reducing the need for expensive surgeries, physician visits and hospitalization.

Medicaid patients should have unrestricted access to all drugs approved by the Food and Drug Administration and prescribed by their physicians. Those medications, after all, contribute to not only the health of the patients, but also to the health of the Medicaid program itself.

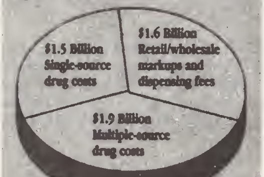
The Role of Prescription Drugs

Medicaid services in fiscal 1988 cost $48.7 billion. Prescription drugs accounted for only $3.3 billion, or 6.7 percent of total spending. On average, the drug cost was $215 for each program recipient.

The prescription drug cost percentage has remained relatively steady in recent years, with

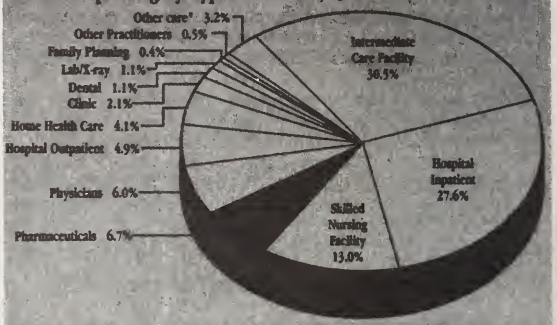
continued on page 2

Medicaid Prescription Drug Expenditures



Projected FY 1991 Medicaid Prescription Drug Expenditures = $5 Billion

Medicaid Spending by Types of Service, 1988



*Other care includes early and periodic screening, rural health clinic services, and miscellaneous other care.

Source: "Pharmaceutical Benefits Under State Medical Assistance Programs," September 1989, National Pharmaceutical Council.

Prescription Drugs and Medicaid: Key Statistics

- Pharmaceuticals account for about 6.7 percent of the total Medicaid budget (includes pharmacists' fees and coverage in most states of some over-the-counter products).
- Single-source or patented drugs amount to only $1.5 billion of the estimated $5 billion cost of Medicaid prescription drug coverage. The sum is less than multiple-source drugs ($1.9 billion) and pharmacy mark-ups and dispensing fees ($1.6 billion).
- In 1989, 16 million people—two out of every three Medicaid recipients—received prescribed drugs under Medicaid.
- The average expenditure per recipient for drugs in 1988 was $215, and the average price per prescription was less than $15.
- About 75 percent of prescription drug payments are for the aged, blind and disabled, and 10 percent are for children.
- Although it is an optional service, every state program has chosen to provide prescription drugs to Medicaid recipients. The programs vary state-to-state. In 19 states, the prescription drug programs include reimbursement restrictions.
- States determine the basic amount to be spent on prescribed drugs. The federal government matches that according to a formula.
- In 1988, Indiana spent more on drugs per Medicaid recipient than any other state, followed by Nebraska, New Hampshire and Georgia. West Virginia spent the least per recipient, followed by Kentucky, California and Mississippi.
- Ninety percent or more of U.S. pharmacies provide drugs to Medicaid recipients. Medicaid is a vendor payment program and pharmacies are paid on a retrospective, fee-for-service basis. Vendor payments for drugs were $3.3 billion in 1988.

continued from page 1

only a slight increase in the average expenditure for pharmaceuticals per patient.

Pharmaceutical Innovation and Research

Having already virtually eliminated such diseases as diphtheria and polio, researchers have turned their sights onto medicines for AIDS, cancer, cardiovascular disease, Alzheimer's and other major ailments. As we enter the 21st Century, research-based pharmaceutical companies are on the brink of yet another surge of innovation.

The success of drug companies is especially impressive when the risk and expense of research are considered. The odds are 4,000 to one against market approval, and discarded experiments, or "dry holes," have contributed to the already high cost of research and development.

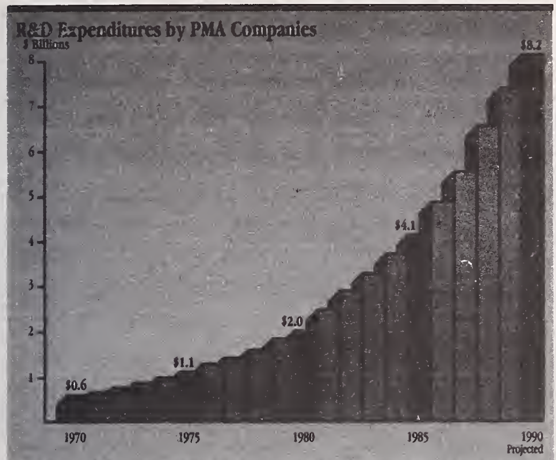
R&D expenditures quadrupled in the 1980s from $2 billion in 1980 to an estimated $8.2 billion in 1990. It now costs an average of $231 million to develop a single drug.

America's research-based pharmaceutical companies spent more than the National Institutes of Health on biomedical research for the first time in 1988, and then repeated the accomplishment in 1989.

Prices and Cost-Effectiveness

Given the many pressures on prescription drug prices today, pharmaceutical costs are surprisingly equitable. Pharmaceutical prices have increased at a rate only slightly higher than the overall Consumer Price Index.

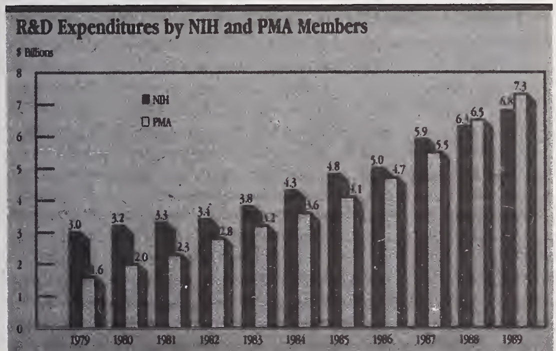
And drugs are cost-effective. They, in fact, are a cost-containment tool when they can be used effectively as alternatives to more expensive surgeries and hospitalizations. Studies and today's scientific literature provide numerous examples of the cost-effectiveness of new medicines.



R&D Expenditures by PMA Companies

The best estimates show that research-based pharmaceutical companies will spend about $8.2 billion on research and development in 1990. R&D expenditures have quadrupled in the past decade, and there is no end in sight to the dramatic increases in research spending. PMA companies, in fact, could end up committing more than $130 billion to research and development through the 1990s.

Source: PMA Annual Survey



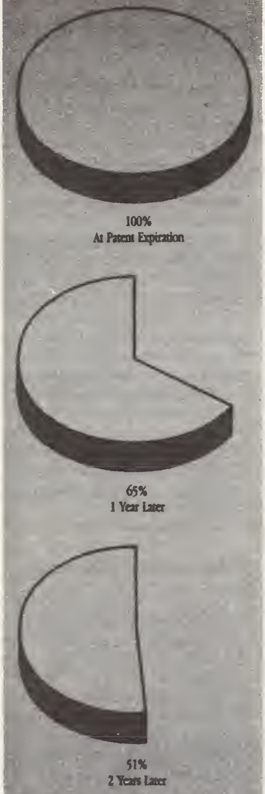
R&D Expenditures by NIH and PMA Members

In 1989, for the second year in a row, PMA company investment in pharmaceutical research and development surpassed total funding by the National Institutes of Health for biomedical research.

Source: National Institutes of Health and PMA Annual Survey

Market Effects of 1984 Law

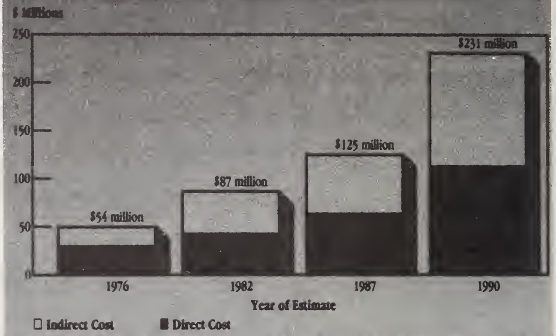
Average Market Share of Pioneer Drugs



The use of generic copies of brand-name drugs has been the central cost-control strategy of the federal government. Congress enacted legislation in 1984 making it easier for generics to gain access to the market. The impact on the pharmaceutical industry has been enormous.

Source: H. Grabowski, Ph.D., Unpublished

Cost of Developing a New Drug

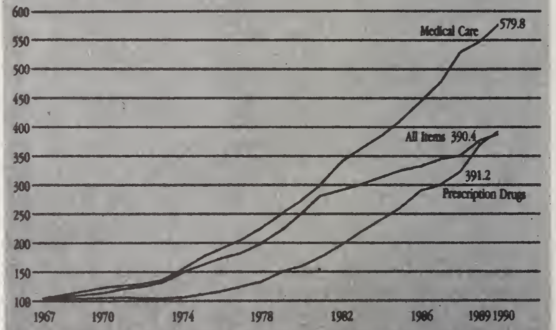


The latest cost estimate for developing a new drug is $231 million, which is more than four times higher than the 1976 estimate of $54 million.

Source: 1976: Ronald Hansen, University of Rochester
1982: Ronald Hansen, University of Rochester, adjusted by PMA for inflation
1987: Stephen N. Wiggins, Texas A&M University
1990: Joseph DiMasi, Tufts University

Rx Drug Prices Compared With Other Indices

Consumer Price Indexes 1967–1990



Prescription drug prices have increased at a rate only slightly higher than the overall Consumer Price Index since the index was set at 100 in 1967. Based on the 1967 benchmark, drug prices today are about two-thirds the overall price index for medical care.

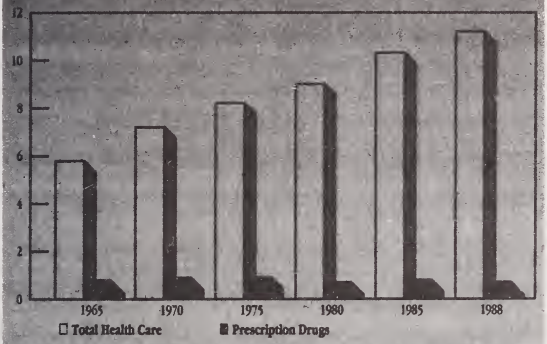
Source: Bureau of Labor Statistics

Drugs as Percent of National Health Expenditures on the Decline

Of every dollar spent on health care, less than seven cents is spent on drugs and sundries. That figure has declined—down from 16.2 cents in 1960—despite the fact that drugs have displaced other more expensive forms of therapy.

While the overall cost of medical care has been an increasing share of Gross National Product (GNP), prescription drugs have been less than one percent of GNP for the past 25 years.

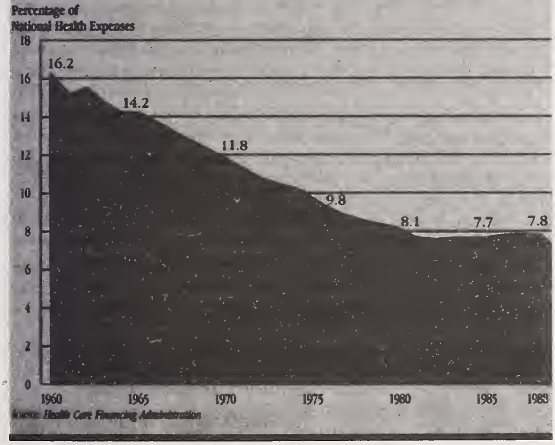
U.S. Health Care Expenditures as a Percent of GNP



Total spending for prescription drugs has stayed under one percent of the Gross National Product (GNP) since 1965, while the percent spent for total health costs has nearly doubled.

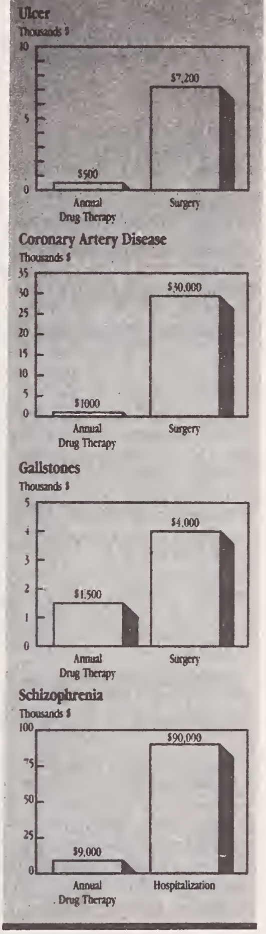
Source: Health Care Financing Administration

Drugs as a Percentage of National Health Care Expenditures (Selected Calendar Years)



Source: Health Care Financing Administration

Treatment Cost Comparison



Pharmaceutical
Manufacturers
Association

1100 15th Street, NW, Washington, DC 20005

ATTACHMENT 4

OPPOSITION TO S.2605
THE PHARMACEUTICAL ACCESS AND PRUDENT PURCHASING ACT OF 1990

Organizations

American Academy of Allergy and Immunology
American Lung Association of Montana
Arkansas Academy of Family Physicians, Inc.
Chemical Industry Council of New Jersey
Detroit Black Nurses Association
Epilepsy Association of Central Ohio
Epilepsy Federation, St. Louis Region
Epilepsy Foundation of Colorado
Epilepsy Foundation of Long Island
Epilepsy Foundation of Philadelphia
Epilepsy League of Lake Superior
High Plains Epilepsy Association
Huntington's Disease Society of America
Medical Society of Delaware
Mexican-American Political Association
Midwestern Congress of Dermatological Societies
Minnesota Chamber of Commerce
Montana Osteopathy Association
National Multiple Sclerosis Society, Michigan Chapter
National Urban League
Texas Osteopathic Medical Association
United States Hispanic Chamber of Commerce

Members of Congress

Honorable Mike Parker, Mississippi, 4th District

Organizations of State Legislators

The Black Elected Democrats of Ohio
Illinois Legislative Black Caucus
Michigan Legislative Black Caucus
Pennsylvania Legislative Black Caucus

State Legislators

Arizona

State Representative Bart Baker, Chairman, Health Committee

Georgia

State Representative E. M. (Buddy) Childers, Chairman, Health and Ecology Committee
State Representative Grace W. Davis
State Representative J. E. (Billy) McKinney
State Representative Tom Wilder

Illinois

State Representative Anthony L. Young, Assistant Majority Leader

Iowa

State Senator Calvin O. Hultman, Minority Leader

Louisiana

State Representative Alphonse Jackson, Jr. Chairman, Health and Welfare Committee

Michigan

State Representative Michael J. Bennane, Chairman, Public Health Committee
Speaker Lewis N. Dodak, House of Representatives

Minnesota

State Senator Linda Berglin, Chair, Health and Human Services Committee
State Representative Brad Stanius
State Senator Donald A. Storm, Assistant Minority Leader

Montana

State Representative Fred Thomas

New Mexico

Speaker Raymond G. Sanchez, House of Representatives

Ohio

Senate President Stanley J. Aronoff
State Senator Grace L. Drake, Chairman, Health and Human Services Committee
State Representative Marc D. Guthrie, Assistant Minority Whip
State Senator David L. Hobson

State Senator Charles F. Horn, Chariman, Economic Development, Science and Technology
State Representative Paul H. Jones, Chairman, Health and Retirement Committee

Rhode Island

State Representative Bradford Gorham, House Minority Leader

South Dakota

State Senator Randy Austad

Tennessee

State Representative Shelby A. Rhinehart, Chairman, Fiscal Review Committee

Texas

State Representative Eddie Cavazos
Speaker Gibson D. (Gib) Lewis, House of Representatives
State Representative Nancy McDonald

ATTACHMENT 5

OPPOSITION TO S.2605 AND OMB PROPOSAL

Organizations

American College of Cardiology/American Heart Association
American Diabetes Association, Arizona Affiliate, Inc.
American Legislative Exchange Council
Arthritis Foundation
Cystic Fibrosis Foundation
Industrial Biotechnology Association
Maine Medical Association
National Black Caucus of State Legislators
National Black Nurses' Association
National Coalition of Hispanic Health and Human Services Organizations
Opportunities Industrialization Centers
Oregon State Council of Senior Citizens
Pharmaceutical Manufacturers Association

State Legislators

Arizona

Senate President Robert B. Usdane

Oregon

State Representative Rick Kotulski, Chairman, Human Resources Committee

South Carolina

Speaker Pro Tempore John I. Rogers, III, House of Representatives

Tennessee

State Senator John N. Ford, Chairman, General Welfare, Health and Human Resources Committee

Utah

Senate President Arnold Christensen

ATTACHMENT 6

Wilmer, Cutler & Pickering
2445 M Street, N. W.
Washington, D. C. 20037-1420

May 25, 1990

MEMORANDUM FOR THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Re: Constitutionality of the Proposed Pharmaceutical Access and Prudent Purchasing Act of 1990

In this memorandum, we consider the constitutionality of Senator David Pryor's proposed Pharmaceutical Access and Prudent Purchasing Act of 1990 (the "Act"), S. 2605. The purpose of the proposed Act is to require the State Medicaid agencies to follow a purchasing procedure designed to obtain rebates from the pharmaceutical manufacturers on drugs previously sold to pharmacies and dispensed by them under the States' Medicaid progams. These requirements would be contained in a new Section 1927 of the Social Security Act.

An essential element of this proposed legislation would require the Secretary of Health and Human Services ("the Secretary") to "contract with a non-governmental entity to establish a National Pharmacy and Therapeutics Committee." Proposed new § 1927(b)(1). The Committee's function would be to review and evaluate scientific information relating to outpatient drugs approved for marketing in the United States, id. at (b)(3), to group each drug "into one or more drug use classes, based upon its medically accepted indications," id. at § (b)(3)(i), and to "identify indications for which two or more covered outpatient drugs are therapeutic alternates and list these drugs in groups of therapeutic alternates within each drug use class," id. at § (b)(3)(iii). The State Medicaid agencies would then be required to negotiate with the manufacturers of these products for rebates on products dispensed to Medicaid beneficiaries. Id. at § (c). Within each product category Medicaid, reimbursement to pharmacies would be restricted to the product of the particular manufacturer that offers a rebate resulting in the lowest net cost. Id. at § (a)(9).

Based on the analysis that follows, we conclude that a court should hold the provisions of the Act relating to the National P&T Committee to be unconstitutional for two reasons: (1) because the establishment of such a Committee would unconstitutionally delegate an important governmental function to a private body, and (2) because the essentially unreviewable discretion granted to the Committee would violate the traditional norms associated with legislative due process.

A. The Proposed Statute

As noted above, the proposed statute would authorize the creation of a National Pharmacy and Therapeutics (P&T) Committee, whose function it would be to group prescription drug products into therapeutic classes, and then, within each class, to identify those particular products that the Committee deems equally safe and effective for each medically accepted purpose.

The National P&T Committee would be comprised of "medical and scientific professionals," Act at § (b)(2)(A),[1] "with recognized knowledge of appropriate utilization of prescription and nonprescription drug therapies, and of the relative safety and efficacy of covered outpatient drug products." Id. The Committee would be a "nongovernmental entity" with which the Secretary of Health & Human Services ("HHS") would "contract" for the performance of its functions. Id. at § (b)(1).[2] The Act provides that, "[w]ithin thirty days

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[1] "In addition to physicians, who shall form a majority of its membership," the Committee is to "have at least one member from each of the following categories of health care professionals": (a) dentists, (b) nurses, (c) pharmacists, (d) experts in geriatric problems associated with drug therapies, (e) experts in pediatric problems associated with drug therapies, (f) experts in psychiatric or neurological problems associated with drug therapies, (g) experts in clinical pharmacology, (h) experts in pharmacoepidemiology, (i) experts in comparative clinical trials of drugs, (j) experts in obstetric problems associated with drug therapies, and (k) other categories of health care professionals that the Secretary or Committee determines should be represented. Id. at § (b)(2)(A).

[2] Given the language of the proposed statute, we assume that the constitutionality of the Act would not be defended on the grounds that the members of the National P&T Committee are government officials, rather than private parties. However, even if the National P&T Committee members were to be recharacterized as government officials, it is clear that the legislation would violate the Appointments Clause of the Constitution.

The Appointments Clause requires that officers of the United States, i.e., "[a]ny appointee exercising significant authority pursuant to the laws of the United States," Buckley v.

(Footnote continued on following page)

of receiving written notice of a determination by the [Committee], the Secretary shall cause the determination to be published for public comment, for not less than sixty days. The Committee shall make appropriate revisions upon consideration of the comments and then transmit a final version to the Secretary . . . ." Id. at § (b)(6)(A). The Act further provides that the "Secretary shall make no changes with respect to the substance of any determinations made by the [Committee] but may comment during the public comment period, and may request reconsideration by the Committee of any determination." Id. at § (b)(6)(B).

The National P&T Committee's listings would be used by multiple-state Medicaid prescription drug buying groups in negotiating prescription drug rebates with the manufacturers of those products. Id. at § (c)(2). The buying group would use the results of these negotiations to identify a "preferred" product in each category -- i.e., a drug available at a price which is determined to offer "superior economic advantages relative to

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[2](Footnote continued from preceding page) Valeo, 424 U.S. 1, 126 (1976), must be appointed either by "the President alone, by the heads of departments, or by the Judiciary." Id. at 132. Because the members of the National P&T Committee are to be nominated and elected by members of the medical and scientific community, it is beyond doubt that the Appointments Clause would not be satisfied. See also Olympic Federal Savings and Loan Assoc. v. Office of Thrift Supervision, No. 90-0482 slip op. at 23 (D.D.C. March 21, 1990) (appointment of director of Office of Thrift Supervision was unconstitutional because made by operation of Congressional statute rather than by an act of the President, the head of any department, or the judiciary).

other drugs in the same drug class." Id. at § (a)(9). Pharmacists would receive Medicaid reimbursement only for these preferred products. Id. at (d)(2). Where a physician has prescribed a non-preferred product for an indication for which a preferred product has been determined to be a "therapeutic alternate" (and the physician has not written a restrictive prescription), pharmacists would be authorized to substitute the preferred product. Id.

In our view, a court should rule that the delegation made by the proposed statute is unconstitutional. The entire statutory scheme would turn on a delegation to the National P&T Committee of the power to make unreviewable discretionary governmental decisions. Indeed, these decisions as to which drugs are therapeutic equivalents are the only decisions contemplated by the statute that require the exercise of substantial judgment and discretion.[3/]

In making its decisions, the P&T Committee is to "continuously review and evaluate existing and newly available scientific and medical information pertaining to the relative safety and efficacy, and the comparability, of covered outpatient drugs approved for marketing in the United States." Id. at

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[3/] The Act would give the Secretary, who would be entitled only to submit comments and request reconsideration of Committee determinations, little more power to affect those determinations than any member of the interested public.

§ (b)(3).[4] It is well known, however, that such determinations of therapeutic equivalency are subject to wide differences of opinion among professional experts. Physicians, clinical pharmacologists, pharmacists, pharmaceutical manufacturers and others often disagree about the extent to which such determinations can accurately be made. These disagreements exist not only across professional lines, but also among practitioners within each of the professions.

While there would be no constitutional objection to the legislative delegation of such subjective judgments to an officer of the executive branch (subject to the degree of judicial review required by due process), there are major constitutional flaws in delegating this task to private citizens -- no matter how well qualified -- without any effective review by an executive branch officer or any opportunity for judicial review.

The proposed statute removes these important determinations from virtually all of the government channels through which such decisions usually are made. It not only bypasses entirely the Food and Drug Administration -- the government body which has heretofore been vested with the responsibility for similar determinations -- but denies even the Secretary of HHS the power to alter the Committee's decisions. And though the statute provides for a period of public comment, it does not require the Committee, after consideration of these comments, to make any statement of the basis and purpose of its determinations. Cf. 5 U.S.C. § 553(c) (rule making procedures under the Administrative Procedure Act). Finally, the statute allows the Committee to make its decisions without any opportunity for judicial review.

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[4] In doing so, the Committee is supposed to "take into consideration, for each drug, mechanisms of action, therapeutic indication, and such other differences among the drugs as the method by which they are metabolized, dosage ranges, known side effects, allergies, toxicities (frequency and type, prevention, risks and benefits), and other special precautions (contraindications and drug-to-drug interactions)." Id.

As we show below, our system of government requires that decisions of such public importance be made by the legislature or delegated to an officer of the executive branch, subject to appropriate judicial review. The proposed statute does just the opposite of that.

I. The Proposed Legislation Would Unconstitutionally Delegate an Important Governmental Function to a Private Body

Although it has been more than fifty years since the Supreme Court has invalidated a congressional delegation of law-making authority to a governmental administrative agency or officer of the executive branch,[5] it seems clear that the Court

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[5] See A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495 (1935) (invalidating § 3 of the National Industrial Recovery Act ("NIRA"), which empowered trade associations to create codes of fair competition approved by the President); Panama Refining Co. v. Ryan, 293 U.S. 388 (1935) (invalidating §

(Footnote continued on following page)

would still invalidate a delegation of such authority to a private body whose decisions were not subject to review by a government officer. While the courts have long recognized the important role that private groups can, and ought, to play in formulating national and state policy, particularly when specialized scientific or technical judgments are involved,[6] the role of private parties has always been seen as an "advisory" rather than a law-making one.[7]

In the leading case on point, Carter v. Carter Coal Co., 298 U.S. 238 (1936), the Court struck down the Bituminous Coal Conservation Act of 1935, which directed private district boards, elected by coal companies, to set minimum prices and fix hours and wages. The Court wrote that legislative delegation to private persons is "legislative delegation in its most obnoxious form." 298 U.S. at 311. The Court went on to say:

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[5] (Footnote continued from preceding page) 9(c) of the NIRA, which directed the President to prohibit transportation of petroleum in excess of the amount permitted by state law).

[6] As Justice Cardozo put it in his concurrence in Schechter Poultry, the "industries of the country are too many and diverse to make it possible for Congress . . . to legislate directly with adequate appreciation of the varying conditions . . . . When the task that is set before one is that of cleaning house, it is prudent as well as usual to take counsel of the dwellers." 295 U.S. at 552 (Cardozo, J., concurring).

[7] In Schechter, Cardozo emphasized that the role of such "dwellers" is to be "strictly [an] advisory" one; it is the "imprimatur of the [elected official] that begets the quality of law." Id.

> The difference between producing coal and regulating its production is, of course, fundamental. The former is a private activity; the latter is necessarily a governmental function . . . . And a statute which attempts to confer such power undertakes an intolerable and unconstitutional interference with personal liberty and private property.
>
> *Id*. at 311.[8]

While the *Schechter* doctrine may have become moribund in cases involving delegation of law-making power to governmental agencies,[9] no subsequent case has weakened *Carter Coal's*

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[8] *See also* Freedman, *Delegation of Power and Institutional Competence*, 243 U. Chi. L. Rev. 307, 332-33 (1976) [hereinafter *Institutional Competence*]:

> [T]he Court's language in *Carter* suggests its recurrent concern with the question of whether private persons, even though they have been selected by Congress, can be relied upon to exercise the sovereign power of the nation with the disinterestedness sufficient to assure that the interests of all of those subject to regulation will receive fair consideration -- consideration of at least the quality and fairness they would receive in a politically accountable legislative forum.

Thus, delegation to a private rulemaking body poses a particularly serious form of the fear that any form of legislative delegation provokes -- namely, that it allows "controversial choices [to be] made without votes being taken and responsibility being publicly assumed by members of Congress." Schoenbrod, *The Delegation Doctrine: Could the Court Give it Substance?*, 83 Mich. L. Rev. 1223, 1244 (1985).

[9] As the Court noted in *Synar v. United States*, 626 F.Supp. 1374, 1384 (D.D.C.), *aff'd sub nom. Bowsher v. Synar*, 478 U.S. 730 (1986):

(Footnote continued on following page)

strictures against delegating such power to purely private entities.

For example, Opp Cotton Mills, Inc. v. Administrator, 312 U.S. 126 (1941), involved a challenge to the Fair Labor Standards Act. The particular program involved called for the setting of minimum wages for particular industries by an officer of the United States "in collaboration with an industry committee" composed of private individuals. Id. at 134. Although it was the committee that investigated industry conditions and determined the appropriate wage to be fixed, the Court ruled that sufficient governmental control was maintained by the Act's requirement that a government officer conduct a hearing and make the actual order: "Thus, under the provisions of [the Act], no wage is fixed which is not recommended by the

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[9] (Footnote continued from preceding page)

> [The Court's] attempts at narrowing [the holdings of Schecter Poultry and Panama Refining], and the Supreme Court's failure to use the delegation doctrine to strike down a statute in fifty years, have led some to conclude that the delegation doctrine is dead, or at least "moribund." The Court has continued to use the doctrine, however, in an interpretive mode, finding that statutory texts conferring powers on the Executive should be construed narrowly where broader construction might represent an unconstitutional delegation. Such cases indicate that while the delegation doctrine may be moribund, it has not yet been officially interred by the Court.
>
> (citations omitted).

committee, and not then without appropriate hearing, findings and order by the Administrator." Id. at 147.

An analogous principle has been expressed in cases involving challenges to the Maloney Act, 15 U.S.C. § 780-3(b)(6), which provides that the National Association of Securities Dealers ("NASD"), a "voluntary association" consisting of private securities brokers and dealers, shall promulgate rules to protect investors and the public. In First Jersey Securities, Inc. v. Bergen, 605 F.2d 690 (3d Cir. 1979), cert. denied, 444 U.S. 1074 (1980), for example, it was argued that the Maloney Act is an unconstitutional delegation of legislative power to a private institution. The Third Circuit rejected this argument on the grounds that, under the statute, the SEC retains the power to "approve or disapprove the Association's rules." 605 F.2d at 697. See also R.H. Johnson & Co. v. Securities and Exchange Commission, 198 F.2d 690, 695 (2d Cir.) (Frank, J.) (Act did not unconstitutionally delegate power to NASD where SEC retained power "to approve or disapprove of the association's Rules"), cert. denied, 344 U.S. 855 (1952).

The courts have also approved of statutes which have incorporated by reference, after review by a governmental body, factual findings or guidelines which were developed by private groups for prior and independent reasons. For example, regulations setting forth a "national consensus standard" promulgated pursuant to the Occupational Safety and Health Act ("OSHA"), 29 U.S.C. § 660(a), are derived in part from standards adopted by the American National Standards Institute ("ANSI"), a private organization. In Noblecraft Industries, Inc. v. Secretary of Labor, 614 F.2d 199 (9th Cir. 1980), these regulations were challenged on the grounds that Congress had improperly delegated legislative and administrative duties to a private group. The court rejected this contention on the grounds that "OSHA in practice did not surrender to ANSI all its standard-making function. As was the case here, it selected among the ANSI standards with apparent discrimination." 614 F.2d at 203.

A similar conclusion was reached by a federal court considering a challenge to a Kansas statute under the Kansas State Constitution. Pursuant to the Kansas Boiler Safety Act, Kan. Stat. Ann. § 44-913 et seq. (1986), the Kansas Department of Resources incorporates by reference a safety code developed by the National Board of Boiler and Pressure Vessel Inspectors, a private organization. The statute was upheld in North American Safety Valve Industries, Inc. v. Wolgast, 672 F. Supp. 488 (D. Kan. 1987). Looking to federal delegation doctrine and separation of powers law as a guide in interpreting the Kansas Constitution, the district court concluded that the statute was not unconstitutional precisely because the rules promulgated by the National Board could be adopted as "Kansas law only after the agency submits the amendment to the secretary of administration and the attorney general [for approval], after notice and a public hearing, and after the legislature examines the amendment." 672 F. Supp. at 493.[10]

Unlike the federal courts, the state courts have had occasion to consider statutes which, like the proposed Pryor bill, make no provision for governmental review of rules made by private groups. Not surprisingly, most of these statutory schemes have been invalidated. See, e.g., Group Health, Ins. of New Jersey v. Howell, 40 N.J. 436, 447, 193 A.2d 103, 109 (1963), supplemented, 43 N.J. 104, 202 A.2d 689 (1964) (statute providing that no corporation can secure certificate of authority to transact business as a medical science corporation without first obtaining approval of corporation's prospective trustees by State Medical Society -- a private group -- is unconstitutional delegation of Legislature's licensing power); State v. Allstate Ins. Co., 231 Mis. 869, 97 So. 2d 372 (1957) (statute may not validly authorize majority of insurance companies authorized to do business in state to fix the rates of agents' commissions); City of Alexandria v. Alexandria Fire Fighters Ass'n, 220 La. 754, 759, 57 So. 2d 673, 675 (1952) (statute fixing maximum hours at 72 per week but making maximum 60 in any city in which a majority of firemen so vote held unconstitutional because legislative function delegated to private group); Fink v. Cole, 302 N.Y. 216, 225, 97 N.E. 2d 873, 876 (1951) (delegating power to license horse owners, trainers and jockeys held to be "such an abdication as to be patently an unconstitutional relinquishment of legislative power"); Hollingsworth v. State Board of Barber Examiners, 217 Ind. 373, 28 N.E.2d 64 (1940) (statute permitting 80% of licensed barbers to fix prices and opening and closing hours held unconstitutional); see also K. Davis, 1 Administrative Law Treatise (1958 ed.) at § 2.14; Abramson, A Fifth Branch of Government: The Private Regulators and Their Constitutionality, 16 Hastings Const. L.Q. 165 (1989); Liebmann, Delegation to Private Parties in American Constitutional Law, 50 Ind. L.J. 650 (1975); Jaffe, Law Making by Private Groups, 51 Harv. L. Rev. 201 (1937) (all reviewing federal and state court decisions regarding delegation to private groups).

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[10] See also State v. Wakeen, 263 Wis. 401, 57 N.W.2d 364, 369 (1953) (statute prohibiting sale of drugs except by registered pharmacists and incorporating definition of "drug" recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, did not violate Wisconsin Constitution's non-delegation doctrine because the "publications referred to in the statute are not published in response to any delegation of power, legislative or otherwise, by the statute. . . . These books were published before the enactment of our statute and not in response to it").

The constitutionality of delegating governmental authority to a group composed in part of private individuals was considered most recently in Melcher v. FOMC, 644 F. Supp. 510 (D.D.C. 1986), aff'd on other grounds, 836 F.2d 561 (D.C. Cir. 1987), cert. denied, 108 S. Ct. 2034 (1988). The case concerned a challenge to the constitutionality of the Federal Reserve Board's Federal Open Market Committee ("FOMC"). A minority of FOMC's membership is chosen by the boards of directors of the several Federal Reserve Banks. The boards consist of private individuals elected by the private banks which own the voting stock of the Federal Reserve Banks. The court considered whether the "type of decision making in which [the FOMC] engages must constitutionally be performed by government officials, or whether, to the contrary, it may validly be performed, at least in part, by otherwise private individuals." 644 F. Supp. at 520. The court, apparently oblivious to the many authorities relevant to the issue, found this to be a question of "first impression." Id. at 520.

The court reviewed the history of the regulation of the nation's monetary system and found a "subtle and conscious balance of public and private elements." Id. at 521. In light of this history, it concluded that "at least some" of the Article I, section 8 power to "coin money" and to "regulate the value thereof" (which the court assumed to be the basis for the open market trading activities engaged in by the FOMC) may constitutionally be delegated to private persons.

Several factors militate against placing too much weight on the result arrived at in Melcher. First, the holding of the case is by its own admission a narrow one, and seems to turn on the peculiar historical role that the banking industry has played in its own regulation and the peculiarly private nature of fixing interest rates. The court expressly noted that it was not deciding "which of the powers entrusted to Congress by Article I, section 8 . . . other than those directly" exercised by the FOMC "may be delegated to private individuals." Id. at 523. The court also noted that the historical involvement of private interests in the banking industry was significant: "Other responsibilities, unlike the functions at issue here, lack a history of private participation, and that fact may well make a significant difference in terms of any attempted delegation to individuals who are not officers of the government." Id. (note omitted).[11]

Second, it is significant that privately appointed individuals make up only a minority of the membership of the FOMC;[12] therefore, unlike a group constituted solely of private

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[11] The history of food and drug regulation in this country is, of course, vastly different from the history of banking regulation. Though the Food and Drug Administration ("FDA") has at times made use of governmental advisory panels, see Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 614-15 (1973) (describing process by which FDA used factual findings of the National Academy of Sciences--National Research Council as a basis for promulgating its own regulations), and has more often than not adopted such recommendations, the ultimate regulatory decisions have always remained in FDA hands. Thus, even under the historical approach suggested in Melcher, the proposed statute would be unconstitutional.

[12] See Melcher, 644 F. Supp. at 512 n. 1 ("the FOMC consists of seven members who hold their offices by virtue of

(Footnote continued on following page)

members, the FOMC could be "captured" by private interests only in highly unusual circumstances. Third, the case was affirmed on grounds entirely separate from the constitutional principles dealt with here.[13] Fourth, by suggesting that the only alternative to a "partnership" between the public and private spheres is "exclusive[]" execution of the responsibilities in question by "government officials," see id. at 523, the opinion ignores the far more common and appropriate subsidiary role that private groups have played as a valued "advisor" to government bodies which ultimately retain control. Finally, as noted, the opinion fails to consider any of the relevant case law on point, including most notably the Supreme Court's opinions in Carter and Schechter Poultry.[14]

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[12] (Footnote continued from preceding page) presidential appointments confirmed by the Senate, and five members who are elected by Reserve Bank boards of directors, and who hold their offices subject to the approval of the Board of Governors").

[13] See Melcher v. FOMC, 836 F.2d 561 (D.C. Cir. 1987) (district court should have exercised its equitable discretion to decline to hear case), cert. denied, 108 S. Ct. 2034 (1988).

[14] This point is also made in Note, The Federal Open Market Committee and the Sharing of Governmental Power with Private Citizens, 75 Va. L. Rev. 111, 152-53 (1989) (criticizing the opinion in Melcher and concluding that "[i]t is not too much to argue that the sharing of governmental authority with private representatives, particularly those with an interest in that area of regulation, fails the constitutional test. The delegation of policy making power to private citizens blurs the line between what is public and what is private . . . . While the FOMC may need the advice and cooperation of the Reserve Banks in setting open market trading policies, that advice can be obtained, and in fact is already obtained in other areas, from the Federal Advisory Council.")

The role envisioned for the National P&T Committee by the Pryor bill is much more than that of an advisor to -- or even a partner of -- the Secretary of HHS. Indeed, the Secretary would expressly be barred from making any "changes to the substance of any determination" made by the Committee. In our view, such legislation would comprise an unconstitutional delegation of power.

II. The Proposed Statute Violates Legislative Due Process

Closely related to the nondelegation/separation of powers concerns expressed in the previous section is the concern that the proposed statute would violate the norms of legislative due process.[15] In Carter Coal, the Court made explicit the connection between the nondelegation doctrine and due process, holding that Congress' delegation of rulemaking authority to private district boards "is so clearly arbitrary, and so clearly a denial of rights safeguarded by the due process clause of the Fifth Amendment, that it is unnecessary to do more than refer to decisions of this court which foreclose the question." 298 U.S.

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[15] Legislative due process is also sometimes referred to as "due process of lawmaking." See Bowsher v. Synar, 478 U.S. 730, 757 n. 23 (1986) (Stevens, J., concurring) ("I have previously noted my concern about the need for a 'due process of lawmaking' . . . . When a legislature's agent is given powers to act without even the formalities of the legislative process, these concerns are especially prominent.") See also Abramson, A Fifth Branch of Government: The Private Regulators and Their Constitutionality, 16 Hastings Const. L.Q. 165, 208-210 (1989); Lind, Due Process of Lawmaking, 55 Neb. L. Rev. 197 (1976).

at 311; See also McGautha v. California, 402 U.S. 183, 272 n. 21 (1971) (Brennan, J., dissenting) ("[a]s applied to the Federal Government, the [delegation] doctrine appears to have roots both in the constitutional requirement of separation of powers . . . and in the Due Process Clause of the Fifth Amendment").

Other courts and commentators have followed suit, suggesting that, even where procedures for notice and comment in administrative rulemaking are not required by statute, the Due Process Clause of the Fifth Amendment nonetheless requires that (at least) certain minimal procedures be observed. See, e.g., Thompson v. Washington, 497 F.2d 626, 634-35 (D.C. Cir. 1973) (Leventhal, J.):

> While many procedural due process cases involve the judicial process, the principles are fully applicable to any executive or administrative forum entrusted with determinations of significant rights. That was held as long ago as Londoner v. City of Denver, [210 U.S. 373] (1908), where the duty of making street improvement assessments and apportioning of taxes was vested in a board of equalization. The Court held that notice and hearing by the board were required before the tax was irrevocably fixed, although "[m]any requirements essential in strictly judicial proceedings may be dispensed with . . . ." [210 U.S. at 386] Application of due process protection to executive and administrative action has followed from recognition of the basic principle that "the constitutional right to be heard is a basic aspect of the duty of government to follow a fair process of decision making." Fuentes v. Shevin, [407 U.S. at 80.]

The demands of legislative due process are particularly strong in cases where the legislating function is delegated to a non-governmental private entity.[16]

The statute proposed by Senator Pryor is no less "obnoxious" than that struck down by the Supreme Court in Carter. The statute would provide for the delegation of an important governmental function to an essentially unaccountable private body which would make its decisions guided by few standards, without any obligation to state the basis and purpose of its determinations, without any provision for judicial review, and without giving the Secretary any power to make substantive changes. The bill offends basic notions of legislative due process in the most profound way.

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[16] As Professor Friedman has observed:

> One of the reasons that delegations of legislative power to the President are so often sustained undoubtedly relates to a recognition of his special character as a delegate. He is a public official, sworn to uphold the Constitution and the laws of the United States, constrained to public spiritedness by the nation's traditions and history's certain judgment, and within the reach of a number of political and finally electoral processes. Rarely are private parties exercising delegated legislative power circumscribed by such profound imperatives.

Institutional Competence, 43 U. Chi. L. Rev. at 334.

Conclusion

We conclude that, on either or both of the grounds set forth above, a court should rule that the Pryor bill's delegation of law-making authority to the National P&T Committee would be unconstitutional.

WILMER, CUTLER & PICKERING

Lloyd N. Cutler
Robert A. Hammond, III
Stuart P. Green

ATTACHMENT 7

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June 20, 1990

Mr. Gerald J. Massinghoff
President
Pharmaceutical Manufacturers' Association
1100 15th Street, N.W.
Washington, D.C. 20005

Dear Mr. Massinghoff:

In reviewing the proposed Pharmaceutical Access and Prudent Purchasing Act of 1990 ("PAPPA") on behalf of a client, we were impressed with its potential impact in malpractice litigation. We would like to share some of our thoughts with you.

The bill sponsored by Senator Pryor has aspects that could adversely affect the litigation prospects of physicians. These problems exist independently of economic considerations in the marketing of prescription drugs. In our view, Senator Pryor's concentration on providing only the lowest priced drugs to participants in Medicaid programs ignores vital interests of physicians, interests that have to be considered if the system of delivering medical care and medication is to be fair and equitable to everyone involved.

As its underlying premise, the bill creates a super committee called the National Pharmacy and Therapeutics Committee, with members immunized from liability and outside the control of the Secretary. The appearance of knowledge, respectability and authority this creates for the Committee will be seized upon by litigants and other interested groups to undercut perfectly reasonable decisions of physicians.

The insidious part of the bill is its command to the committee that for each indication it is to determine whether there are one or more drugs "that should be considered first whenever a patient presents the indication" and to designate drugs which are "therapeutic alternates." This from a committee not accountable to anyone for its choice. All it has to do is publish its choices for comment. Neither the Commissioner nor anyone else would be able to do anything to change or object to the choices except to submit a comment during a 60 day period after publication of the committee's conclusions. No opportunity to be heard or review process is contemplated. The negotiating groups are then obligated to make those drugs "preferred."

When the committee selects a drug that is best for each indication "whenever a patient presents the indication," or decides whether a drug is a therapeutic alternate, the bill is obviously substituting the Committee's opinion for the prescribing choice of the physician to whom the patient presents the indication. While there is no justification for believing this type of "blue ribbon" committee could adequately match the particular patient's history and present condition with an optional drug choice,[1] the effect of its selection of the best among drugs, on the basis of its conclusions of "superior safety and efficacy," presents the physician with a liability dilemma. From a liability (and ethical) standpoint, the physician is placed in peril no matter what his decision.

If the physician chooses to prescribe a drug other than the one the committee selects, then in the event of litigation alleging harm from the drug, the plaintiff would argue that the committee designation is proof that the physician choose a drug that was less safe and efficacious. While physicians face the reality of defending their choice today, the bill would inject an added element into the process, when admitted in evidence, by which plaintiff's testifying experts can claim than an expert committee, charged with the duty to decide for the government which drug provides superior safety and efficacy for a particular indication, has confirmed their testimony that the drug prescribed was not the best or safest choice.

On the other hand, if the physician prescribes the drug designated by the committee, he has not protected himself from liability. While he has the benefit of an argument that the committee's determination of safety and effectiveness is meaningful evidence that the prescribing decision was correct, he faces experts testifying for the plaintiff who will contend that a physician has a nondelegable duty to choose the correct drug based only on what is best for the particular patient, not on conclusions of a committee of persons who never saw the patient, nor on purely economic grounds. The attack here is reversed, arguing that only the physician seeing the patient is in a position to know what is safe and effective for that patient. It would be argued that the prescriber failed to satisfy this duty by choosing the wrong drug.

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[1] The committee would be appointed from among persons with "recognized knowledge" of drug therapies and of the "relative safety" of drug products. But experience has shown that despite impressive titles some persons who are thought of as having "recognized knowledge" are not as well acquainted with the drugs and current information as many prescribing physicians.

For any indication, all drugs other than the one selected by the committee as superior for safety and efficacy, using a test of relative safety, are relegated to second class status if courts and jurors accept the committee's selection as meaningful. This would probably be the case, since the committee would have government-like authority. .

The impact of the bill in litigation could not be confined to Medicaid prescriptions. It is probable that the physician's problem of overcoming the consistancy between the committee conclusion and opinions by plaintiffs' witnesses would be present in a wide variety of situations, not just those involving Medicaid.

Very truly yours,

William P. Richmond, P.C.

WPR:cjd

ATTACHMENT 8

May 22, 1990

Pharmaceutical
Manufacturers
Association

SENATOR PRYOR'S PRESCRIPTION DRUG LEGISLATION (S. 2605)

Background. Senator David Pryor has introduced a bill based on the premise that Medicaid can save money by switching patients' drug therapies to the cheapest product in a therapeutic class.

The Senator's basic premise is wrong. Distinct drugs within the same therapeutic class are not routinely interchangeable. Rather, such drugs are chemically different and are not equally safe and effective for each patient. S. 2605 would establish restrictive formularies under which some drugs would be readily reimbursed and others would not, with these results --

- Medicaid patients would receive second-class medical treatment. Reimbursable drugs for Medicaid would be chosen by cost, not by value to the specific patient for the specific illness. Medicaid patients would face long delays in having their prescriptions filled--pending required physician/pharmacist discussions on switching to the low-bid drug--and in many instances would only receive a three-day supply of the prescribed drug if the pharmacist could not reach the physician.

- Medicaid costs would rise, not fall. S. 2605 requires a new higher reimbursement level for pharmacists, extensive drug utilization review programs in every state, enlarged federal and state bureaucracies, frequent market surveys and extensive administrative procedures--all of which will be costly and are likely to offset any drug budget savings. Moreover, studies show that restrictive formularies increase total Medicaid costs by 4 to 15 percent, because those who are denied drug therapies may require more expensive alternative treatment such as additional physician services, hospitalization or surgery.

- Policies of three major organizations of state legislators would be ignored. The Council of State Governments, the National Black Caucus of State Legislators, and the American Legislative Exchange Council have each endorsed Medicaid coverage of all FDA-approved drugs. Utah, Oregon, South Carolina and Louisiana have recently chosen to join the majority of states that have broad drug coverage ("open formularies").

May 22, 1990

- Incentives for pharmaceutical research and development will be reduced. U.S. firms are now investing over $8 billion annually in research and development, more than is spent on health research by the entire National Institutes of Health. By adding arbitrary factors and another layer of bureaucracy at the end of an already-lengthy process of drug development and approval, the Pryor bill would lessen the value of patents and make pharmaceutical research less attractive to investors. New biotechnology companies would be especially vulnerable to investor concerns about a bureaucratic system which arbitrarily determines winners and losers.

S. 2605 suffers from a number of major shortcomings, which are discussed in more detail on the following pages.

May 22, 1990

Nongovernmental National Pharmacy and Therapeutics ("NP&T") Committee

The Secretary of HHS would be required to contract with a private party for the establishment of a NP&T Committee which--operating wholly outside of regular government decision-making processes--would identify "therapeutic alternates within each drug use class," i.e., those prescription drugs which "can be expected to have a similar therapeutic effect when administered to patients in a therapeutically equivalent dosage."

The findings of the NP&T Committee would not be subject to modification or reversal by any official of the Executive Branch, including the Secretary of HHS, the Surgeon General, the Assistant Secretary of Health, and the Commissioner of Food and Drugs.

Recognizing the inherently dangerous nature of attempting to select "therapeutical alternates" among different chemical entities, S. 2605 provides that no member of the NP&T Committee "shall be civilly liable to any person" because of actions taken in the performance of the functions of the Committee.

PMA's Comments:

An inherent flaw in this scheme is the underlying premise that entirely different drugs having unique chemical structures are somehow therapeutically interchangeable among patients who may present vastly different patient profiles. Even among pharmaceutical equivalents (different forms of the same active chemical) scientific literature concludes that there are marked differences in efficacy, required dose, bioavailability, pharmacokinetic profile, contraindications, and incidence of adverse side effects.

Although hospitals limit the number of drugs in their inventories, cost is only one factor in deciding what to stock. Moreover, the hospital setting provides numerous patient safeguards that would be absent from a national, low-bid-based outpatient formulary. Indeed, thirty-one states have chosen not to adopt restrictive drug lists for Medicaid.

A second major problem with the NP&T Committee provisions is that delegating these decisions to non-federal officials would violate the Constitution. The decisions of the NP&T Committee are binding on the states and would involve the health of over 20 million Medicaid patients, and hundreds of millions of dollars of prescription drug sales. Those decisions must be made in accordance with regular government decision-making processes with the inherent safeguards of the Administrative Procedures Act, the Federal Advisory Committee Act, federal conflict-of-interest standards and the Freedom of Information Act.

Because thousands of critical decisions are required of the NP&T Committee, it is understandable why one would want to avoid the administrative burdens that accompany the observance of due process, but anything less than that will not satisfy constitutional requirements.

May 22, 1990

State Negotiating Programs

The bill would establish a negotiating program in which states would be divided into five different groups: (1) those with their own "grandfathered" restrictive drug programs; (2) those which negotiate individually; (3) members of multi-state buying groups; (4) members of a federal buying group, and (5) states which contract out the responsibility for negotiations to private organizations or to federal agencies.

"Grandfathered" states would be permitted to continue restrictive prescription drug policies, including "prior authorization programs" which require doctors to request special case-by-case permission to prescribe various drugs for their Medicaid patients. Non-grandfathered states would be required to rely upon the findings of the National P&T Committee with respect to which drugs are "therapeutic alternates," but other states would be permitted to establish their own, individual P&T Committees which could make findings different from the National P&T Committee. Non-grandfathered states would negotiate with the manufacturers of each group of "therapeutic alternates" to determine which one offers "superior economic advantages relative to other drugs in the same class...," whereas other states could continue their pre-existing programs.

In those states where bidding occurs, the successful bidder (most likely the one offering the largest rebate) in each class would become the "preferred drug" for purposes of Medicaid reimbursement. The so-called preferred drug could be an over-the-counter product in those state Medicaid programs which cover such products.

PMA's Comments:

This process is clearly cumbersome and confusing. Moreover, in grandfathering some existing state programs, the bill will allow the continuation of some of the most burdensome and painful restrictions now in effect, including "prior authorization programs," which require doctors to file detailed requisition forms--which often languish for weeks and sometimes months in the bureaucracy--in order to get patients the medications they need.

And, while the bill purports to require that at least one drug in each class be available to Medicaid beneficiaries, its grandfathering of "prior authorization programs" makes this requirement easily circumventable.

May 22, 1990

Substitution of Low-Bid Drug

If a physician wrote a prescription for a non-low-bid or "non-preferred" drug and did not write "[brand name] medically necessary," the pharmacist would be required to call the physician for permission to substitute the so-called "preferred drug." If after "diligent efforts" the physician could not be reached, the pharmacist would be permitted to dispense "no more than a three-day supply of the non-preferred drug" and must continue to attempt to contact the prescriber or another physician responsible for the patient's care.

PMA's Comments:

In 1990, approximately a quarter-billion prescriptions will be written for Medicaid patients. If just a fraction of those prescriptions required a telephone call-back before a pharmacist could substitute a low-bid drug, the administrative burden would be enormous; and presumably "diligent efforts" would require more than one telephone call and the passage of a substantial period of time in many cases.

Moreover, since many drugs are prescribed for more than one diagnosis or disease, a drug could be a low-bid or "preferred" drug if prescribed for one purpose, but not for another. Because the diagnosis is not written on a patient's prescription, a call would be required in many instances simply so that a pharmacist could learn what the diagnosis is, and thus which class of drugs to consider for substitution.

Most importantly, the idea that a Medicaid patient would frequently receive only a three-day supply of the prescription drug greatly complicates pharmaceutical therapy and serves to underscore the second-rate level of care this proposal presents for economically disadvantaged people.

Providing a patient with a limited supply of a prescribed drug would at best cause considerable inconvenience and at worst could create serious physical problems for the patient who finds it difficult or impossible to return to the pharmacy for the balance of the medication.

In many cases this system would result in the interruption of essential medication therapy. The delays, hardships and round-trips to the pharmacy brought about by the verification and partial-dispensing requirements would be especially burdensome for older Americans and single parents with sick infants or children. The problems for patients would be especially unacceptable in poor rural areas with inadequate public transportation.

May 22, 1990

Higher Reimbursement for Pharmacy

Caps on pharmacy reimbursement now applied by most states would be removed. Instead, S. 2605 requires that state Medicaid programs reimburse pharmacies at the regular retail price, up to the "90th percentile" of such prices in the state.

In calculating retail prices for purposes of payments to pharmacies, the states are specifically prohibited from taking into account any pharmacy discounts given to large providers -- such as those which are typically given to nursing homes or HMOs.

PMA's Comments:

On their own initiative, or under prodding from HCFA, most states have amended their Medicaid programs so that pharmacies are reimbursed under a formula designed to approximate actual wholesale acquisition cost of the product, plus a dispensing fee.

By eliminating these caps, S. 2605 will add substantially to overall Medicaid costs and overrule by legislative fiat the ongoing efforts by HCFA and the states to control pharmacy reimbursement.

Pharmacy services currently account for about one-fourth of the total Medicaid drug budget. In California, which has the country's largest Medicaid program, pharmacy fees and mark-up claimed 38 cents out of every prescription drug dollar in 1989.

Moreover, by specifically barring the states from looking at pharmacy discounts--which are often given to nonprofit organizations, HMOs, nursing homes, and other preferred provider organizations--the bill virtually guarantees that only the highest retail pharmacy charges will be used to measure "actual charges" for purposes of payments to pharmacists under Medicaid. Meanwhile, in surveying manufacturer prices, the bill requires manufacturers to disclose prices "available to any nonprofit entity...."

May 22, 1990

Drug Utilization Review

The Pryor bill would require each state to establish a Drug Utilization Review Board, to be responsible for implementing a prospective and retrospective Drug Utilization Review (DUR) program, in order to "educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care...."

In addition, the bill would require each state to establish, through quality control peer review organizations or local medical societies, ongoing educational programs "to assure ready availability to physicians and pharmacists of information concerning which covered outpatient drugs are (A) judged by the National Pharmacy and Therapeutics Committee to be (i) accepted for given therapeutic indications, and (ii) therapeutic alternates, and (B) designated as preferred drugs in the state."

These educational programs would be "targeted toward problems or individuals identified in the course of the prospective and retrospective drug utilization reviews ...."

PMA's Comments:

All parties concerned share an interest in eliminating fraud, abuse and other inappropriate practices that involve the expenditure of federal funds. However, a fair reading of this section makes clear that the objective of drug utilization review is not to discourage inappropriate prescribing but rather to discourage the prescribing of "non-preferred," i.e., non-low-bid drugs.

Since the entire thrust of this legislation is to encourage the prescribing of the cheapest drug in any given therapeutic class, it is fair to say that S. 2605 will have a significant impact on those physicians who regularly use their independent judgment to prescribe what they determine is the best medication for their patients, not what the government determines is a so-called "preferred drug" based on a bidding system.

May 22, 1990

Negating Privately Owned Patents

In a provision unrelated to Medicaid, S. 2605 would allow the Secretary of HHS, if he disapproves of the method chosen by a manufacturer to distribute a drug, to apply the provisions of 28 U.S.C. 1498--until now limited exclusively for use of a patented invention "by or for" the Government--to purchases of pharmaceutical products by "nursing homes ... and appropriate selected outpatient pharmacies." In order to make these purely commercial transactions feasible, S. 2605 would authorize the FDA to apply procedures designed to approve manufacture and marketing of generic copies of drugs whose patents have expired, so that a non-licensed source of manufacture and sale could be established in order to infringe the patent.

PMA's Comments:

Section 1498 is an exception to the United States patent laws and allows the Government to infringe, or to authorize its contractors to infringe, U.S. patents in order to provide goods or services to the Federal Government, upon payment of a reasonable royalty to the patentee. The Section was never intended to authorize infringement of patents except "by or for" the Federal Government, and has never been interpreted to permit such infringement. S. 2605 would force pharmaceutical manufacturers to distribute their products through distribution channels which they have, for reasons of public health and safety, determined to be inappropriate.

ATTACHMENT 9

OPPOSITION TO JUNE 20, 1990 MEDICAID PROPOSAL BY THE OFFICE OF MANAGEMENT AND BUDGET

Organizations

Alliance for Aging Research
American Academy of Family Physicians
American Heart Association New Jersey Affiliate
American Medical Association
American Psychiatric Association
American Society of Clinical Pharmacology and Therapeutics
American Society of Consultant Pharmacists
American Society of Hospital Pharmacists
American Society of Internal Medicine
Arizona Medical Association
Association of Biotechnology Companies
Black United Fund of Houston
Coalition Against Therapeutic Substitution
Epilepsy Foundation of America
Heritage Foundation
Illinois Retired Teachers Association
League of United Latin American Citizens
Massachusetts Medical Society
National Foundation for Ileitis and Colitis
National Hemophilia Foundation
National Medical Association
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Rainbow Coalition
New England Hemophilia Association
New Jersey Business & Industry Association
New Jersey Health Products Council
New Mexico Medical Society
Oregon Medical Association
Pennsylvania Thoracic Society
Tennesseans for Sensible Medicine
Texas Medical Association

Members of Congress

Joint Letter of Opposition by Members of the House of Representatives

Honorable Jim Chapman, Texas, 1st Dist.
Honorable George W. Crockett Jr., Michigan, 13th Dist.
Honorable Bernard J. Dwyer, New Jersey, 6th Dist.
Honorable Harris W. Fawell, Illinois, 13th Dist.

Honorable Harold E. Ford, Tennessee, 9th Dist.
Honorable Pete Geren, Texas, 12th Dist.
Honorable Charles A. Hayes, Illinois, 1st Dist.
Honorable Dale E. Kildee, Michigan; 7th Dist.
Honorable Peter H. Kostmayer, Pennsylvania, 8th Dist.
Honorable Thomas A. Luken, Ohio, 1st Dist.
Honorable Thomas J. Manton, New York, 9th Dist.
Honorable Robert J. Mrazek, New York, 3rd Dist.
Honorable James L. Oberstar, Minnesota, 8th Dist.
Honorable Major R. Owens, New York, 12th Dist.
Honorable Donald M. Payne, New Jersey, 10th Dist.
Honorable Nancy Pelosi, California, 5th Dist.
Honorable Charles B. Rangel, New York, 16th Dist
Honorable Bill Richardson, New Mexico, 3rd Dist.
Honorable J. Roy Rowland, Georgia, 8th Dist.
Honorable Gus Savage, Illinois, 2nd Dist.
Honorable James H. Scheuer, New York, 8th Dist.
Honorable Philip R. Sharp, Indiana, 2nd Dist.
Honorable Louise Slaughter, New York, 30th Dist.
Honorable Louis Stokes, Ohio, 21st Dist.
Honorable Esteban E. Torres, California, 34th Dist.
Honorable Edolphus Towns, New York, 11th Dist.
Honorable Morris K. Udall, Arizona, 2nd Dist.
Honorable Tim Valentine, North Carolina, 2nd Dist.
Honorable Craig A. Washington, Texas, 18th Dist.

Also

Honorable James H. Quillen, Tennessee, 1st Dist.

Organizations of State Legislators

Tennessee Black Caucus of State Legislators

State Legislators

Arizona

Speaker Jane Dee Hull, House of Representatives
State Senator Doug Todd

California

State Senator Alfred E. Alquist, Chairman, Budget and Fiscal Review Committee

State Senator Diane E. Watson, Chairperson, Health and Human Services Committee

Illinois

State Senator Aldo A. DeAngelis, Assisant Minority Leader
State Representative Ted E. Leverenz
State Representative Alfred G. Ronan

Missouri

Speaker Bob F. Griffin, House of Representatives
State Senator James L. (Jim) Mathewson

New Hampshire

State Representative Roland Sallada

New Jersey

Assemblyman Wayne R. Bryant, Majority Leader
Assemblyman Joseph M. Kyrillos, Jr.

Tennessee

State Senator Jerry W. Cooper
State Representative Paul M. Starnes, Chairman, Special Joint Committee on Medicaid

Texas

State Representative Barry Connelly, Chairman, Budget and Oversight
State Representative Paul J. Hilbert

Mr. WAXMAN. Thank you, Mr. Mossinghoff. The rest of the statement will be in the record in full.

Pass the microphone to Mr. Zabriskie.

STATEMENT OF JOHN L. ZABRISKIE

Mr. ZABRISKIE. Good afternoon, Mr. Chairman, members of the subcommittee.

I am Dr. John L. Zabriskie, president of Merck, Sharp & Dohme, the U.S. prescription drug division of Merck & Co., Inc. We appreciate the opportunity to testify on legislative proposals concerning Medicaid prescription drug reimbursement and the policy of equal access.

Merck is the world's largest discoverer and developer of prescription drugs. In the past 10 years, we introduced 23 new products to treat serious diseases. Over $855 million R&D commitment this year alone is over 10 percent of the entire industry effort. In the last 10 years, we have invested $4.5 billion in research.

Merck has been introducing breakthrough medications the last 50 years to treat or prevent pernicious anemia, arthritis, high blood pressure, elevated cholesterol, many childhood and adult infectious diseases, and congestive heart failure.

In addition, we have improved on the breakthroughs of others to eliminate drug interactions, reduce side effects, enhance efficacy and help ensure greater compliance. Several of our products are true orphan disease drugs which treat perhaps only 100 patients and at nominal price levels.

Most importantly, the dollars we will spend this year on R&D include massive programs aimed at AIDS, Alzheimer's disease, osteoporosis, prostatic disease and other illnesses.

Merck fully supports the goal of helping the Nation's poor gain equal access to the prescription medicines they need. Earlier this year, we voluntarily introduced a new program to the Nation's State Medicaid programs to address the need. It is called the Merck Equal Access to Medicines Plan.

By it, each State is given the benefit of Merck's best price to any U.S. customer, a cost reduction of $20 million or more. In turn, States open their formularies to all Merck single source products.

We are gratified to report that our program has such merit that already, 32 States have adopted the program and 10 more have written us they intend to adopt it. This represents over 90 percent of the Medicaid population and expenditures.

Our program is working, Mr. Chairman, within the free market system and without any unnecessary constraints. We believe the success of the Merck program and discount initiatives by other major firms at the State level may suggest Federal legislation now is unnecessary.

Nevertheless, we have developed a Federal legislative proposal which we believe builds upon our State Equal Access Program. Our written submission fully details our proposal. It affords to each State Medicaid program the firm's best price on single source products in exchange for access of a firm's full line of products to Medicaid. It guarantees a minimum savings of 10 percent on ingredient costs. The plan is fair to patients, to taxpayers and to manufacturers.

Mr. Chairman, the simplicity of the Merck plan is obvious. The program requires no significant administrative costs, no new data, no new paperwork or bureaucracy.

Insofar as other legislative proposals are concerned, we see much that we can support. In particular, we share with Congressmen Wyden and Cooper and Senator Pryor the two major goals of his legislative proposals: Allowing Medicaid to obtain the best price and giving Medicaid patients access to the best medicines.

We also endorse other specific proposals he has made including DUR and the prevention of arbitrary cuts in pharmacy reimbursement.

But we do have serious reservations about other provisions. Of great concern to us, and a feature we will strenuously oppose, is indexing each product's current best price to the Consumer Price Index.

We are also concerned about the open access provision in the recent congressional legislative proposals.

This morning, Congressman, you talked about the need for no formulary and no P&T's committees. We also heard about the Georgia patient that lost a stomach because of restrictions in the State of Georgia.

That was due to prior approval system where the dosage was reduced. That is what gives us the greatest pause for your legislation today, that is, it would allow States to impose prior authorization requirements on products of manufacturers that have submitted rebates.

Our experience to date with the Merck program clearly shows us that it is meeting the needs of the States, patients and ourselves in a satisfactory manner. Should Congress conclude that legislation is required, then the Merck plan is a desirable approach. It is fiscally sound, it is good public health policy, it is fair. It will work and it is in the public interest today and for the future.

Thank you.

[Testimony resumes on p. 648.]

[The prepared statement of Mr. Zabriskie follows:]

Testimony of Dr. John L. Zabriskie, Jr.
President – Merck Sharp & Dohme

House Energy and Commerce Committee
Subcommittee on Health and Environment

September 14, 1990

Good morning. Mr. Chairman, members of the Subcommittee, I am Dr. John L. Zabriskie, President of Merck Sharp & Dohme, the U.S. prescription drug division of Merck & Co., Inc. We appreciate the opportunity to testify on legislative proposals concerning Medicaid prescription drug reimbursement and the policy of equal access.

Merck is the world's largest discoverer and developer of prescription drugs. In the past ten years, we introduced 23 new products to treat serious diseases. Our $855 million R&D commitment this year alone is over 10 percent of the entire industry effort. In the last 10 years, we have invested $4.5 billion in research.

Merck has been introducing breakthrough medications and vaccines for over fifty years to treat or prevent pernicious anemia, arthritis, high blood pressure, elevated cholesterol, many childhood and adult infectious diseases, and congestive heart failure. In addition, we have improved on the

BREAKTHROUGHS OF OTHERS TO ELIMINATE DRUG INTERACTIONS, REDUCE SIDE EFFECTS, ENHANCE EFFICACY AND HELP ENSURE GREATER COMPLIANCE. SEVERAL OF OUR PRODUCTS ARE TRUE ORPHAN DISEASE DRUGS WHICH TREAT PERHAPS ONLY A HUNDRED PATIENTS AND AT NOMINAL PRICE LEVELS. MOST IMPORTANTLY, THE DOLLARS WE WILL SPEND THIS YEAR ON R&D INCLUDE MASSIVE PROGRAMS AIMED AT AIDS, ALZHEIMER'S DISEASE, OSTEOPOROSIS, PROSTATIC DISEASE AND OTHER ILLNESSES.

MERCK FULLY SUPPORTS THE GOAL OF HELPING THE NATION'S POOR GAIN EQUAL ACCESS TO THE PRESCRIPTION MEDICINES THEY NEED. EARLIER THIS YEAR, WE VOLUNTARILY INTRODUCED A NEW PROGRAM TO THE NATION'S STATE MEDICAID PROGRAMS TO ADDRESS THE NEED. IT IS CALLED THE MERCK EQUAL ACCESS TO MEDICINES PROGRAM. BY IT, EACH STATE IS GIVEN THE BENEFIT OF MERCK'S BEST PRICE TO ANY U.S. CUSTOMER - A COST REDUCTION OF $20 MILLION OR MORE. IN TURN, STATES OPEN THEIR PROGRAMS TO ALL MERCK SINGLE SOURCE PRODUCTS. WE ARE GRATIFIED TO REPORT THAT OUR PROGRAM HAS SUCH MERIT THAT ALREADY 32 STATES HAVE ADOPTED THE PROGRAM AND 10 MORE HAVE WRITTEN US THEY INTEND TO ADOPT IT. TOGETHER, THESE 42 STATES ACCOUNT FOR OVER 90 PERCENT OF THE MEDICAID POPULATION AND EXPENDITURES.

OUR PROGRAM IS WORKING, MR. CHAIRMAN -- WITHIN THE FREE MARKET SYSTEM AND WITHOUT ANY UNNECESSARY CONSTRAINTS. WE BELIEVE THE SUCCESS OF THE MERCK PROGRAM AND DISCOUNT INITIATIVES BY OTHER MAJOR FIRMS AT THE STATE LEVEL SUGGESTS FEDERAL LEGISLATION NOW IS UNNECESSARY. NEVERTHELESS, WE HAVE DEVELOPED A FEDERAL LEGISLATIVE PROPOSAL WHICH WE BELIEVE BUILDS UPON OUR STATE EQUAL ACCESS PROGRAM IN A MANNER FAIR TO ALL CONCERNED. OUR WRITTEN SUBMISSION FULLY DETAILS OUR PROPOSAL. BRIEFLY, IT HAS SEVERAL FEATURES: IT AFFORDS TO EACH STATE MEDICAID PROGRAM THE FIRM'S BEST PRICE ON SINGLE SOURCE PRODUCTS IN EXCHANGE FOR ACCESS OF A FIRM'S FULL LINE OF PRODUCTS TO MEDICAID. IT GUARANTEES A MINIMUM SAVINGS OF 10 PERCENT ON INGREDIENT COSTS. THIS PLAN IS FAIR TO PATIENTS, TO TAXPAYERS AND TO MANUFACTURERS. LET ME EXPLAIN WHY.

FIRST, OUR PLAN ENSURES THAT MEDICAID PATIENTS WOULD HAVE ACCESS TO ALL FDA APPROVED DRUGS, NOT JUST A MINIMUM OF ONE IN A CLASS AS HAD BEEN PROPOSED BY OTHERS.

SECOND, OUR PLAN WILL SAVE TAXPAYERS AND THE FEDERAL MEDICAID PROGRAM OVER $170 MILLION IN FISCAL YEAR 1990-1991. FROM FISCAL 1991 THROUGH 1995, WE ESTIMATE TOTAL SAVINGS OF $1.4 BILLION FROM SINGLE-SOURCE DRUGS ALONE. ALL OTHER SAVINGS -- FROM MULTI-SOURCE PRODUCTS AND DRUG UTILIZATION REVIEW -- WOULD BE ADDITIVE. ATTACHED TO MY PREPARED REMARKS IS A TABLE ILLUSTRATING HOW THE SAVINGS WOULD OCCUR.

THIRD, TAXPAYERS' DOLLARS ARE NOW PURCHASING OUR PRODUCTS FOR MEDICAID AT THE BEST PRICE WE CHARGE ANY CUSTOMER.

LASTLY, OUR PLAN ASSURES THAT ALL MANUFACTURERS CAN PARTICIPATE IN THE MARKET. PLANS WHICH ARTIFICIALLY LIMIT THE NUMBER OF DRUGS IN A GIVEN CLASS ARE NOT ONLY BAD MEDICINE AND POOR SOCIAL POLICY, BUT ARE INHERENTLY UNFAIR TO OUR INDUSTRY.

MR. CHAIRMAN, THE SIMPLICITY OF THE MERCK PLAN IS OBVIOUS. THE PROGRAM REQUIRES NO SIGNIFICANT ADMINISTRATIVE COSTS, NO NEW DATA, NO NEW PAPERWORK OR BUREAUCRACY. EXISTING DATA IS SENT TO THE FIRM, A REBATE IS CALCULATED AND A QUARTERLY CHECK IS SENT TO EACH STATE.

INSOFAR AS OTHER LEGISLATIVE PROPOSALS ARE CONCERNED, WE SEE MUCH THAT WE CAN SUPPORT. IN PARTICULAR, WE SHARE WITH SENATOR PRYOR THE TWO MAJOR GOALS OF HIS LEGISLATIVE PROPOSALS: ALLOWING MEDICAID TO OBTAIN THE BEST PRICE AND GIVING MEDICAID PATIENTS ACCESS TO THE BEST MEDICINES. WE ALSO ENDORSE OTHER SPECIFIC PROPOSALS HE HAS MADE, INCLUDING DUR AND THE PREVENTION OF ARBITRARY CUTS IN PHARMACY REIMBURSEMENT.

BUT WE DO HAVE SERIOUS RESERVATIONS ABOUT OTHER PROVISIONS. OF GREAT CONCERN TO US -- AND A FEATURE WE WILL STRENUOUSLY OPPOSE -- IS INDEXING EACH PRODUCT'S CURRENT BEST PRICE TO THE CONSUMER PRICE INDEX. THIS WOULD AMOUNT TO PRICE CONTROLS AND

WOULD BE UNFAIR TO THOSE SEVERAL MANUFACTURERS THAT CURRENTLY PROVIDE LARGE DISCOUNTS TO CERTAIN LIMITED MARKETS.

WE ARE ALSO CONCERNED ABOUT THE OPEN ACCESS PROVISION IN THE RECENT CONGRESSIONAL LEGISLATIVE PROPOSALS. WE DO NOT BELIEVE THIS PROVISION, AS CURRENTLY DRAFTED, ACHIEVES THE GOAL OF OPEN ACCESS BECAUSE IT PERMITS STATES TO IMPOSE PRIOR AUTHORIZATION REQUIREMENTS ON THE PRODUCTS OF MANUFACTURERS THAT HAVE SUBMITTED REBATE AGREEMENTS. THIS REQUIREMENT COULD NEGATE THE OPEN ACCESS FEATURE.

WITH RESPECT TO BOTH OF THESE ISSUES AND OTHER CONCERNS WE HAVE, WE WOULD APPRECIATE THE OPPORTUNITY TO WORK WITH STAFF IN DEVELOPING APPROPRIATE LANGUAGE.

OUR EXPERIENCE TO DATE WITH THE MERCK PROGRAM CLEARLY SHOWS US THAT IT IS MEETING THE NEEDS OF THE STATES, PATIENTS AND OURSELVES IN A SATISFACTORY MANNER. SHOULD CONGRESS CONCLUDE THAT LEGISLATION IS REQUIRED, THEN THE MERCK PLAN IS A DESIRABLE APPROACH. IT IS FISCALLY SOUND, IT IS GOOD PUBLIC HEALTH POLICY, IT IS FAIR. IT WILL WORK AND IT IS IN THE PUBLIC INTEREST TODAY AND FOR THE FUTURE.

THANK YOU.

Summary of Medicaid Equal Access to Medicines and Best Price Discounts Act of 1990

The Medicaid Equal Access to Medicines and Best Price Discounts Act of 1990 requires pharmaceutical manufacturers to provide discounts on all of their single-source prescription drugs to the Medicaid program of every state as a condition of federal matching funds for those products. States are prohibited from restricting access to the single-source prescription drugs of manufacturers that commit to provide such discounts.

The Act adds a new section 1927 to the Social Security Act with the following provisions:

* The States must guarantee equal access to all single-source prescription drugs of manufacturers that have submitted Medicaid discount commitments. No formulary, prior authorization, or other restrictions can be imposed on such drugs that are different from restrictions generally imposed on all drugs under the State Medicaid program.

* Manufacturers will be given the opportunity to submit a commitment to the Secretary of Health and Human Services to provide discounts to the Medicaid program of every state on all of their single-source prescription drugs. Any commitment will be required to last for at least one year and could be renewed.

* The discount will be an amount necessary to ensure that Medicaid receives the best price offered to any entity in the United States, subject to a minimum discount of at least 10 percent of the aggregate Medicaid expenditures on the manufacturer's drugs in each State. In addition, there is a phased-out ceiling on discounts of 15 percent in the first two years, 20 percent in the third and fourth years, and 25 percent in the fifth year.

* Discounts shall be calculated by the manufacturer based on utilization data provided by State Medicaid agencies. Discounts shall be paid by the manufacturer to each State Medicaid agency on a quarterly basis. The States must deduct the amount of the discount from their medical assistance expenditures for purposes of determining the amount of Federal matching funds.

* No Federal matching funds will be provided with respect to any drugs of any manufacturer that has not submitted a discount commitment. There is an exception for drugs determined to be medically necessary in accordance with State procedures. States are not required to cover any drugs for which Federal matching funds are not available.

WHITE PAPER
ON A FEDERAL APPROACH
TO MEDICAID DRUG COSTS

SEPTEMBER 12, 1990

The debate on the future of Medicaid reimbursement for medicines has reached a critical point. Rising Medicaid costs and an enormous Federal deficit have led to a search for savings. Several proposals have thus far surfaced on the Federal level — two by Senator Pryor (S.2605), one by the Office of Management and Budget and a number by pharmaceutical firms. Some proposals would establish national formularies or drug lists for the purpose of determining what medicines Medicaid patients will receive through a winner-take-all bidding process among manufacturers. Such proposals suffer from serious shortcomings that would deny access of the poor to needed medicines and interfere with the physician's ability to effectively treat his or her patients.

Merck recently offered its own approach at the state level — the Merck Equal Access to Medicines program. The basis of this program is the granting of Merck's best price to state Medicaid programs which have open access to all Merck single-source medicines. Generic product cost controls are left untouched. In the short time since its announcement, the program has been accepted by thirty-two states and 10 others wrote to us of their intent to sign our agreement (representing over 90% of Medicaid patients nationwide) with the balance of the states still evaluating our offer. The widespread support the plan has received indicates their desire to keep access open to medicines particularly when savings can be achieved. In order to address the Federal deficit problem, Merck is proposing that its state Equal Access to Medicines program be adopted at the national level with the following provisions:

- Manufacturers will either commit to provide substantial discounts to Medicaid in every state on all of their single-source prescription drugs or opt out of the federally funded portion of the program. Any commitment will be required to last for at least one year and could be renewed indefinitely.

- The discount will be an amount necessary to ensure that Medicaid receives the best price offered to any entity in the United States, subject to a minimum discount of at least 10 percent of the aggregate Medicaid expenditures on the manufacturer's drugs in each state. There is a phased-out ceiling on discounts of 15 percent in the first two years, 20 percent in the third and fourth years and 25 percent in the fifth year to avoid penalizing firms with extremely deep discounts in the first few years.

- Discounts will be calculated by the manufacturer based on utilization data provided by state Medicaid agencies. Discounts will be paid by the manufacturer to each state Medicaid agency on a quarterly basis. The states deduct the amount of the discount from their medical assistance expenditures for purposes of determining the amount of Federal matching funds.

- No Federal matching funds will be provided with respect to drugs of any manufacturer that has not submitted a discount commitment. If a unique drug is determined to be medically necessary in accordance with state procedures, the state may retain it in its program even absent a discount, however, states are not required (nor expected) to cover any drugs for which Federal matching funds are not available.

- The States must guarantee equal access to single-source prescription drugs of manufacturers that have submitted discount commitments. No formulary, prior authorization or other restrictions can be imposed on such drugs that are different from restrictions generally imposed on all drugs under the state Medicaid program.

The analysis below highlights the advantages of the Merck program.

The Merck proposal would improve patients' access to medicines.

Under the Medicaid Equal Access to Medicines and Best Price Discounts Act, patients would receive the best possible medicines for their ailments. The principle that the poor and the disadvantaged should be treated as well as the more fortunate in the face of serious disease is reaffirmed, reversing the patient impact in some states of the long delays before new medicines are approved for reimbursement. Discrimination in the quality of patient care would be prevented and the attendant economic and social costs of the discrimination avoided.

In contrast, by establishing a national formulary covering only the cheapest drug within a therapeutic class, other proposals would severely restrict the Medicaid patients' access to medicines.

The Merck proposal would avoid the dangers of therapeutic substitution and prevent any interference in how physicians treat their patients.

The Merck proposal would ensure that physicians can prescribe and pharmacists dispense the most effective medicine for their patients. Existing restrictions on needed therapies would be removed. More importantly, therapeutic substitution -- which is opposed by major medical associations and patient groups — would be avoided.

The Merck proposal would leave untouched the 600,000 prescription transactions which occur each day within the Medicaid system.

The belief that access will be preserved and burdens avoided by allowing the physician to use a handwritten phrase to assure use of the medicine actually desired is, unfortunately, misplaced. In fact, such procedures result in only a few percentage handwritten overrides and even then physicians are often accused of wasting taxpayers' money for exercising their judgment. In states such as California with prior approval systems for non-formulary drugs, the same "safety-valve agreement" loses credibility since it is generally recognized to be unworkable in practice given the thousands of transactions to be effected each day. If the goal is to assure the best medicine for the individual patient, the override mechanism does not work.

The Merck proposal would produce an estimated $307 million in rebates in FY 91 for the states and the Federal government through manufacturer discounts.

The Merck proposal would produce over $300 million in rebates on single-source products alone commencing realistically as soon as October 1, 1990. This estimate is based upon its ease of implementation and calculations along the following lines: Excluding over-the-counter drugs, multi-source drugs and the pharmacists' portion of Medicaid drug expenditures, manufacturers of single-source prescription drugs receive about 38% of Medicaid expenditures. Using this percentage and an estimate of $5.6 billion in FY 91 Medicaid drug expenditures, the modified best price approach would produce $307 million in rebates on single-source products alone.

This savings level represents a proportionately fair contribution by single-source drug manufacturers to achieving the proposed Medicaid drug budget reduction target. The discounts would be encouraged by a general Federal policy of denying matching funds to states for non-discounted drugs. Because the maximum discount would increase to 20% in the third and fourth year, 25% in the fifth year and unlimited thereafter, the overall savings would increase substantially each year.

The Merck proposal provides the potential for avoiding indirect costs in other services due to drug restrictions and for achieving savings in overall treatment costs.

The Merck proposal takes advantage of the potential for drug therapy to cut overall health care costs by reducing hospitalization, physician visits, etc. This principle is supported by many states that have maintained open formularies. It has also been supported by various studies including the comparative analysis of open and closed Medicaid formularies conducted by Louisiana State University economists (William Moore and Robert Newman), which suggests higher Medicaid costs in closed formulary states of 4-15%. A decrease of only 0.5% in total Medicaid costs resulting from removing access barriers in restrictive formulary states could yield savings of over $750 million in FY 91 alone.

The Merck proposal takes advantage of the competitive marketplace without requiring complex administrative structures and addresses the concerns raised by some that the best price proposal is unfair to some manufacturers.

The modified best price proposal supported by Merck ensures that over time Medicaid will achieve the best price charged by manufacturers for their medicines. We believe the best price concept is the fairest approach to a government program for the poor. As modified, however, the Merck proposal assures that the Medicaid program will receive a 10% discount and thus has savings potential regardless of manufacturer pricing practices. Additionally, for those who have argued that the best price approach is unfair to those firms with large discounts, the legislation provides a phase-in feature that assures that companies will not have to provide discounts greater than 25% until 1996.

The OMB proposal and S.2605 are significantly different. They seek to exact price concessions and cost reductions through the actual exclusion (not the threat of exclusion) of many manufacturers and many medicines from the Medicaid sector. To do so, elaborate administrative structures for bidding and negotiation would be required at considerable cost. The administrative structure for any formulary and medically necessary override process would also be of daunting expense given the medical judgments required.

Conclusion

In sum, the Merck Equal Access to Medicines and Best Price Discounts Act represents a policy direction which is fair to patients, the taxpayer, industry and the Medicaid program. It also has the best chance of achieving savings which could be realized as soon as October 1, 1990, while improving the access of Medicaid patients to needed medicines.

WHITE PAPER

FEDERAL BUDGET IMPACT: MEDICAID BEST PRICE/EQUAL ACCESS PROPOSAL

SEPTEMBER 12, 1990

This paper describes the multi-billion dollar budget deficit reducing impact of the Medicaid best price/equal access proposal by Merck for single-source pharmaceuticals. Our analysis is in two parts: overview of the marketplace dynamics and financial analysis of the Merck proposal. We have also attached "questions and answers" which illustrate the practicality of the system proposed by us.

I. Marketplace Dynamics

In contrast to many healthcare sectors, the pricing structure in the pharmaceutical industry is primarily a function of the private sector market forces rather than government reimbursement policy which has only a small impact. This is because government reimbursement of outpatient drugs under the Medicaid program represents only about 10% of the outpatient U.S. prescription drug revenue of most manufacturers. The remaining 90% is made up of sales to (a) government institutions, including the Veterans Administration, Defense Personnel Support Center and state hospitals and prisons; (b) a few score HMOs which operate their own pharmacies; (c) 7,000 hospitals, and (d) the retail sector consisting of a dozen large chain buyers, a few very large mail order firms and fifty thousand independent and small chain retailers. Virtually all Medicaid, HMO and insurance industry managed care drug plan reimbursement is made to and through the retail sector. In turn, over 70% of retail sector sales are through wholesalers, four of which share well over 50% of the market. From the manufacturer's perspective, the marketplace is made up of a group of powerful buyers (the VA, HMOs, hospital chains) whose volume and ability to influence physician decisions is significant; a group of large volume buyers (wholesalers, chains and mail order) and everybody else.

II. Financial Analysis

The Merck plan has several features designed to simplify any financial analysis of its impact on Medicaid spending. A brief summary of the financial analysis is included as Table One.

A. Prompt Effective Date

The program can be implemented in full and savings accrue immediately upon legislative enactment. Our highly successful state program which already covers to date about 90% of Medicaid patients for our single-source products became effective July 1, 1990, and in some states was made retroactive when details were worked out after July 1. We assume full implementation of the federal program could occur effective October 1, 1990.

B. Minimal Administrative Costs

The program relies wholly on existing Medicaid utilization data gathered by states to determine reimbursement to pharmacies. No additional paperwork other than the forwarding of copies (usually data tapes) to manufacturers would be necessary. To the extent states elect to simplify their programs (reassigning formulary review personnel and the like) administrative costs could be reduced or the resources applied to more effective areas such as educational DUR programs. We, therefore, assume no administrative cost.

C. Certainty of 10% Discount

The program includes a 10% discount floor. Thus, a manufacturer with no price concessions must nevertheless pay back to Medicaid 10% of Medicaid's ingredient reimbursement. In the 1990-1991 federal fiscal year, this 10% floor guarantees minimum payments of over $200 million to Medicaid (56% of which goes to federal budget reduction). In future years the 10% minimum remains in place, thus payments will go up each year regardless of the cause for growth in the Medicaid drug plan (technology, utilization, eligibility, product mix and inflation). Only the occurrence of patent expirations and general price cuts (e.g. Noroxin® in 1989) reduce the base off which payments are made.

Note that the "reference price" off which the 10% discount minimum is calculated is a real number which can be readily verified from manufacturer or wholesaler business records.

D. Ceiling Phase Out

The Merck plan migrates towards affording each firm's best price for Medicaid over a five-year period. If a manufacturer's best prices in the aggregate are more than 10% below the reference price, then that greater discount is what must be refunded to Medicaid. The phase-in of 15 to 25% ceilings is included solely to cushion the adverse financial impact on those manufacturers which may currently provide substantial discounts on major products. As discussed below, it is widely recognized manufacturer best prices to DPSC currently are quite frequently 30% or more below the defined reference price. Given these discounts currently in place and the unlikelihood that they can or would be substantially modified in less than a few years time (see the Q&A, attached) we assume 90% of Medicaid volume would be at the ceiling discount during the next five years and 10% of volume (reflecting those few firms with minimum discounts) at the 10% minimum. Based on this, Medicaid budget reductions will be, in fact, over $300 million in 1990-1991, growing to well over $700 million in 1994-1995. (See Table One, lines H and I, attached.)

E. Open Formulary Impact

If all states were required to open their formularies to all single-source products, we anticipate drug program costs will increase by $50 to $100 million. As discussed in the next paragraph, it must be stressed that this additional cost to the drug program is very likely offset by savings on other healthcare expenditures. For clarity, we have analyzed our proposal with and without such a spillover benefit. (See Table One, line K and line M.) California, Kentucky, West Virginia, Mississippi and Alabama would bear most of this increase. California alone constitutes about two-thirds of the increase because of its many years of increasing formulary restrictions. California has added few products in the past few years — even significant therapeutic improvements have been delayed. Entire disease categories and therapeutic approaches have had no formulary approved product for extended periods of time. California's system, we believe, works to the detriment of the Medicaid patient.* We also note that California has adopted our state program and a similar Glaxo program entailing the addition of several major products and has adopted legislation which also may significantly open its formulary (and, thus, add to federal Medicaid costs) regardless of the adoption of any federal equal access plan.

Studies suggest an open formulary saves total healthcare dollars versus a tightly restrictive formulary. Estimates frequently cite savings of several percent. We have used the very conservative figure of a 0.5% total budget savings applicable to the Medicaid program in the nineteen states commonly identified as being restrictive. This assumption adds two-thirds of a billion dollars in total program savings in the first year alone.

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* We have argued against this healthcare policy by Medi-Cal and have fought to change it at every juncture. It seems to us inappropriate that the cost increase to California from making its program more open should be calculated as a reduction in the "value" of our program.

ROH:crm:3908e

8/21/90

Questions and Answers

Q 1: Why Best Price/Phased-in Ceilings?

A: The heart of our proposal is the phase-in of a best price product-by-product discount. The phase-in caps of 15% growing to unlimited caps in year six are solely to soften any financial shock which may be borne by the industry members with selectively significant discounts on certain major products.

The magnitude of the best price discount can be gleaned by comparing publicly available DPSC prices versus manufacturer actual selling prices to wholesalers ("reference price" in our proposal). An examination is likely to reveal that for a significant number of firms' major products on contract to the DPSC the average discount exceeded 30%. Since these contracts run one to three years and cannot be readily terminated, we believe the 1990-1991 actual savings under our plan will be very close to or equal the 15% temporary ceiling. The Medicaid savings, therefore, is over $300 million in 1990-1991, not just the $220 million calculated by reliance on the 10% minimum provision discussed above.

In future years the value of the savings will probably increase as the ceiling increases to 25% in 1994-1995 and unlimited thereafter. Given that current discounts are significantly higher than 25% and given that buyers such as the VA, DPSC, HMOs, hospitals and others are (1) protected from reduced discounts by multi-year contracts; (2) collectively several times larger than Medicaid and singly similar in size, and (3) shrewd negotiators, we conclude that it is reasonably likely that the 25% ceiling will be reached in future years for many manufacturers which will not be able to generally narrow these best price discounts already negotiated. Accordingly, Medicaid should be able to reduce its single-source ingredient costs by about 25%.

The base for calculating the discount is the manufacturer-controlled best price and the manufacturer-controlled reference price. This suggests the discount may be illusory. In fact, it is very real. The best price is the actual best price in contracts with real customers. The DPSC, VA, Kaiser HMO, etc. are not likely to engage in chicanery to raise or obscure their best price deal with a manufacturer. Given that a typical manufacturer may have dozens or hundreds of such contracts, any contrary assumption is untenable. We have also carefully drafted the best price definition to help preclude any major loopholes. The reference price is the catalog price charged wholesalers (over 75% of pharmaceuticals flow through wholesalers). Were a manufacturer to raise the catalog price, the discount to the government would be that much greater.

Were the manufacturer to lower the catalog price to reduce the best price discount calculation towards the 10% floor, the result would be financially catastrophic since the 90% of the business reduced in price would obviate the reduction in the Medicaid discount by nine-fold. Thus, the manufacturer has every reason to have an accurate reference price as well as best price.

Q 2: Won't the industry simply raise their best prices to be closer to the reference price?

A: This is a possible strategy though not without pitfalls and impracticalities. First, manufacturers typically have dozens or hundreds of contracts with various government, HMO and other purchasers. They may run for one to even five years. Those with government agencies may not be realistically terminable. Such contracts may include price protection clauses and restrictions on the allowed annual increase. If even only one of these "best price" contracts remains in effect, then the manufacturer is obliged to provide Medicaid with the discount (which is always at least 10% anyway). Second, the customers which obtained the best prices are not likely to be solicitous of the manufacturer which seeks to narrow its discounts by increasing prices to the favored customer more than the general public. Third, if one manufacturer does temporarily succeed in greatly narrowing discounts but others don't choose to do so, then competitive forces will inexorably pressure the one to relent.

Q 3: Won't the industry simply raise prices and, thus, the cost to Medicaid by the amount of the rebates?

A: It can't. Remember, unlike other healthcare sectors such as hospitals, Medicaid pays for only 10% of the pharmaceutical marketplace. Medicaid is a third party payer so there is no way for manufacturers to selectively raise their price to Medicaid. If Medicaid gets discount payments of $300 million, the industry would have to charge about $3 billion in extra price increases to everybody to result in Medicaid paying back to the firms the $300 million. Whatever imperfections exist in the marketplace, it is unlikely that the industry could increase prices by an additional 10 to 15% this year over and above current price increase percentage levels.

Q 4: Won't the industry "game" the defined reference price?

A: It can't. Suppose a firm artificially raised the "reference" catalog price charged to wholesalers. The effect would be to increase the discount owed to Medicaid — the exact opposite result that gaming would intend (also, large wholesalers would not likely participate in such a subterfuge and an invoice-based survey or audit would uncover it immediately). A reduction in the reference price to reduce the Medicaid discount would be a boon to the non-Medicaid 90% of the market and financially ruinous to the manufacturer.

Q 5: Won't the industry "game" the defined best price?

A: We believe the definition of best price is sufficiently loophole-free so that it cannot be "gamed." Other experts are invited to draft it differently.

Q 6: Is the discount a phantom?

A: No. It is very real. Indeed, Merck will rebate substantially more than $20 million to Medicaid in calendar year 1991 under our state program. A federal program applying to all manufacturers will result in a magnitude increase over the Merck state program.

Q 7: Why will manufacturers join in the program?

A: The manufacturer has no real choice. If it joins in the program, it stands to "lose" 1.5% of revenue (the 10% Medicaid market times a 15% discount). If it opts out of the new program, there will be no matching funds on any of the manufacturer's products in any state. The individual states, under intense budget pressure, will certainly refuse reimbursement as well. The manufacturer will, therefore, lose 10% of its revenue rather than only 1.5%, face a public and government relations nightmare and likely lose sales in the private sector as well. The choice is voluntary simply as a matter of constitutional law and public policy. The only possible holdout might be a privately-owned firm which elects to treat the matter as an issue of profound principle.

Q 8: Won't new drug technology, which must be reimbursed under the plan, bankrupt Medicaid?

A: No. For the past two decades only about twenty new drugs have been approved by the Food and Drug Administration each year (and many are non-Medicaid in-patient products). Of the twenty, only a handful have significant sales. That handful is made up of drugs that are especially useful and appropriately priced. They are almost always covered by Medicaid (except California in recent years). In the twelve months following FDA approval, Medicaid's share of purchases of the twenty or so new drugs seldom exceeds $25 million and would largely be incurred whether or not there were an "equal access" program. Much of the $25 million is not in fact incremental since new products displace (cannibalize) older product usage. Incidentally, most commentators and Congress believe new technology is vital to America's competitive strength and should be encouraged, not discouraged. Also, most new drugs save on other healthcare costs so the above noted $25 million cost is a myopic "drug budget only" viewpoint.

Q 9: Won't states simply spend the discounts on other program benefits or administration, thus negating the federal budget reduction?

A: The Merck proposal explicitly prevents this.

Q 10: Will the proposal work?

A: Merck is implementing a virtually identical program in many states at this moment and expects to have the program in place virtually everywhere later this year unless superseded by federal legislation. There can be no doubt about the feasibility of the program, unlike far more complex, often untried and controversial alternatives that have been suggested (and some of which have, when tried, repeatedly failed heretofore on the state level).

Q 11: What about multisource products, pharmacy fees, DURs and other issues?

A: Our proposal addresses single-source drugs because that is the industry segment we know best. Others with far more expertise (and a direct interest) should be consulted on such issues, the inclusion of which would likely complement our proposal.

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TABLE ONE

MERCK PROPOSAL FINANCIAL ANALYSIS

(IN MILLIONS)

		FY 91	FY 92	FY 93	FY 94	FY 95
A.	Medicaid Drug program	5600	6500	7400	8500	9700
B.	Federal Portion (56% of A)	3136	3640	4144	4760	5432
C,	Rx Expenditures (Minus 10% OTC)	2822	3276	3730	4284	4889
D.	Pharmacists' Portion (Fee + Markup = 30%)	847	983	1119	1285	1467
E.	Total Rx Manufacturer Ingredient Cost (C-D)	1975	2293	2611	2999	3422
F.	Generic Rx Manufacturer Ingredient Cost (40% of E)	790	917	1044	1200	1369
G.	Single-Source (S-S) Rx Ingredient Cost (E-F) (38% of Total Costs)	1185	1376	1567	1799	2053
H.	Federal Savings of Best Price	172	200	274	315	410
I.	State Savings	135	187	216	248	323
J.	Ingredient Cost of Open Formularies	(50-100)	(50-100)	(50-100)	(50-100)	(50-100)
K.	Medicaid Drug Budget Impact of Merck Plan (H+I-J)	207-257	257-307	390-440	463-513	633-683
L.	Potential Added Savings From Opening Formularies in 19 Closed States, Assuming only 0.5% Decrease In Total Medicaid Costs	779	877	979	1093	1216
M.	Total Medicaid Budget Impact (K+L)	988+	1134+	1369+	1556+	1849+

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An Analysis of Merck, Sharp, and Dohme's Equal Access to Medicines Program

Merck, Sharp, and Dohme's Equal Access to Medicines program is a responsible approach to reducing Medicaid drug costs while preserving and even enhancing access to health care for the nation's poor and disabled citizens. Merck's plan is an efficient and equitable way to achieve savings, and it would not jeopardize public health.

The Merck program is superior to Senator David Pryor's Pharmaceutical and Prudent Purchasing Act of 1990 (S.2605) on several grounds:

- A preliminary analysis of the expected savings from the Merck proposal on single-source drugs suggests that they would probably significantly exceed the expected savings from single-source provisions in the Pryor proposal.

- Administrative costs under the Merck proposal would be negligible while the Pryor bill would call forth a complicated bureaucratic structure that would entail substantial administrative costs. These costs could easily approach, and could even exceed the expected savings from the Pryor bill.

- The Merck program would improve access to prescription drugs by opening formularies across the nation. In contrast, the Pryor proposal would limit access to drugs by effectively limiting the drugs to one in each therapeutic class. The open formulary proposal might raise costs slightly in the drug portion of the Medicaid program, but would lower total Medicaid costs in the long-run by reducing medical services in such areas as physician and hospital care.

- The Merck proposal would not interfere with timely access to prescriptions. The Pryor bill's therapeutic alternates provisions would interrupt the flow of drugs to Medicaid patients and create barriers to getting prescriptions filled.

- The Merck proposal is not likely to be "gamed," and the savings achieved are not likely to be substantially offset by higher prices to other customers.

- Overall estimates of the savings from the Pryor bill are significantly greater than the estimates for the single-source drug component of the bill. Yet the larger total includes savings from better management of the Medicaid program through such mechanisms as electronic claim management and drug utilization review. These measures could be linked up with a variety of different proposals to reduce prices -- including the Merck proposal.

The issue of estimated savings is now further explored.

Estimated Savings

A variety of assumptions are needed to cost out any of the drug price reduction proposals -- Pryor, Merck, and those put forward by other manufacturers. The company proposals are no less "scorable" than the Pryor proposal, and may actually be more readily evaluated. Both sets of proposals require assumptions about dynamic market responses, and the Pryor bill also requires difficult estimates of administrative costs, as well as rather arbitrary assumptions about such matters as the proportion of times a physician will exercise the "override" option.

In determining expected cost savings from its proposal, Merck has started with an estimate of $5.6 billion for the FY 1991 Medicaid drug market. By deducting estimates of over-the-counter drugs, the fees and markups of pharmacists, and the generic manufacturers' ingredients costs from this total, and by accounting for the fact that the federal share of Medicaid expenditures is 56 percent, the company arrived at an estimate of single-source prescription ingredient costs of $1.185 billion for FY 1991.

Merck then assumed that 10 percent of this total, or $118.5 million, would be subject to the minimum 10 percent discount, yielding $11.8 billion in federal savings, while 90 percent of the total, or $1.067 billion, would be subject to first-year maximum discount of 15 percent, yielding another $160 million. The total first-year federal savings amount to the sum of these figures, or $172 million. State savings in FY 1991 then become $135 million. These estimates, of course, assume that the Merck proposal is adopted industry-wide.

Using similar assumptions suggesting that the rising cap (20 percent in years two and three and 25 percent in years four and five) would be binding on most sales, Merck estimates that federal savings would rise to $274 million in FY 1993 and $410 million in FY 1995. State savings would rise to $323 million in FY 1995. The Merck estimate of federal savings in FY 1993 -- $274 million -- can be contrasted with NDP's estimate of FY 1993 savings for the Pryor bill -- $15-76 million.

The Merck assumptions seem reasonable in light of the prevalence of substantial discounts in the Medicaid drug market today. In fact, current discounts often exceed the 25 percent cap scheduled for 1994 and 1995.

It is unlikely that these savings would be dissipated through corporate "gaming." Even if manufacturers wanted to game the system by artificially hiking up their reference prices, most buyers would not participate in such a scheme, and it could be readily discovered in an audit. Moreover, raising the reference price would deepen the Medicaid discount, which is the opposite of the result desired from a gaming strategy.

Furthermore, it is unlikely that Medicaid discounts would be significantly offset by price increases to other buyers. Medicaid cannot control the drug market, with other buyers left vulnerable and helpless. For this type of gaming strategy to work, Medicaid would have to be the price-setter, with other buyers serving as relatively passive "price-takers." But Medicaid accounts for only about 10 percent of most manufacturers' outpatient drug revenues. The rest of the market includes some large buyers with strong market power (e.g., the Veterans Administration, the Defense Personnel Support Center, large chain drug buyers, large mail order houses) and thousands of smaller purchasers. Some of these large buyers pool their buying power into one central source, thereby enhancing it. Medicaid does not do this.

As noted earlier, many of these buyers have already negotiated large discounts from drug manufacturers, and would not just give them up so as to accommodate Medicaid's need to achieve savings. They have too much market power to permit this type of cost-shifting.

Furthermore, the prevalence of long-term contracts would preclude compensating price increases in many Medicaid drug transactions. Contracts running one to three years, with buyer price protection clauses, are common, and some contracts run as long as five years.

For all these reasons, we believe that the projected savings from the Merck proposal are real, not illusory. We believe that they are "scorable" in the federal budget process.

Costs/Savings of Open Formulary Provisions

Any attempt to score the open access provision of the Merck proposal is a difficult enterprise, in terms of estimating both the level of increased drug use and the decreased expenditures for non-drug services that might result from greater availability of drug therapy. Merck includes an offset of $50-100 million for the added drug costs arising from an open formulary. The company also projects added savings from opening formularies in 19 states, assuming a 0.5 percent decrease in total Medicaid costs. This reflects the likely decline in physician visits and hospital admissions accompanying the less restrictive posture toward prescription drugs. The projected added savings are $779 million in FY 1991, rising to $1.2 billion in FY 1995.

These estimates seem reasonable, and probably by design, conservative, in view of the fact that there is research evidence suggesting that offsetting system savings could amount to 4-15 percent of the total Medicaid budget (Merck uses 0.5 percent). Yet these projections are more speculative than the direct cost savings associated with price reductions. Research evidence on the indirect savings is suggestive of large benefits, but not yet definitive. While the open formulary benefits may turn out to be more important in the long-run, it would be more difficult to make a case to score them as savings in the federal budget process.

Mr. **Waxman**. Thank you, Mr. Zabriskie.

Mr. Ingram.

STATEMENT OF ROBERT A. INGRAM

Mr. **Ingram**. Thank you, Mr. Chairman.

My name is Robert A. Ingram. I am executive vice president for Glaxo. I appreciate this opportunity to discuss Glaxo's discount proposal.

Glaxo has devoted considerable effort to finding ways that we can help alleviate the financial burdens on Medicaid and assure access to medicines for the poor. We are here today because we are in the process of providing the Medicaid system with significant cost savings.

Glaxo has offered to give to Medicaid the best discount on single-source pharmaceutical products that we offer to any commercial customer which, like Medicaid, reimburses pharmacies for filling prescriptions for patients. These include managed health care customers, such as IPA and network model HMO's and PPO's. These reimbursing managed care providers are the most analogous commercial customers to Medicaid.

We have offered our discount program to every State that provides a drug benefit to Medicaid beneficiaries. We have contracted with a number of State Medicaid agencies to provide them with our discounts and are in the process of negotiating several more such contracts.

Glaxo's discount proposal, because it is referenced to contracts with the highly competitive reimbursement segment of the managed care industry, makes it difficult for manufacturers to raise prices to Medicaid in future years. Discounts for these reimbursers are assured by contracts of several years' duration. The pressures of the free market will keep them in place in the foreseeable future.

We believe that our proposal results in a fair and equitable discount that will provide significant savings for Medicaid. Our discounts in the reimbursing segment of the managed care market are as high as 20 percent and average about 15 percent.

Glaxo does not believe that the so-called "best price" offered by pharmaceutical manufacturers to any customer is a fair or reasonable reference for discounts to Medicaid. We recognize that the term "best price" is an appealing phrase.

However, for most manufacturers, the "best price" is the price provided to the Department of Veterans' Affairs. These discounts, which, according to the Senate Aging Committee, are as high as 90 percent, are an historical anomaly that has grown out of World War II efforts to bolster the Government's access to needed medicines.

Prices in the market have remained artificially low in part because companies like Glaxo have found it reasonable to give veterans a break in a very small portion of our business.

Companies that have provided generous discounts to the Government in the past should not be penalized for saving taxpayers' dollars. If Medicaid discounts were pegged to the DVA price, companies that offer only small discounts or no discounts at all to the

Federal Government would be rewarded. By contrast, those companies that over the years have offered deeper discounts to the DVA would be greatly disadvantaged.

There are other customers who receive discounts larger than the reimbursing segment of managed care. However, these customers, unlike the reimbursing segment and unlike Medicaid, buy in large quantities, warehouse our products in their own facilities, and dispense to patients out of their own inhouse pharmacies.

As a result of the Glaxo proposal, significant savings are currently being achieved by States without the need for Federal legislation. We understand that the States are having considerable success in achieving Medicaid savings with several other companies besides Glaxo.

In light of the activity at the State level, we believe that the wisest course for Congress, at the present time, would be to issue a broad directive to the States to achieve savings in drug budgets over the next year and to report the results of these savings to Congress at the end of the year.

This would allow each State agency to obtain the savings in a manner most appropriate to that State. It also would be consistent with the premise of Medicaid, in which the Federal Government issues guidelines to be implemented as the States see fit.

Glaxo favors providing the Medicaid system with significant cost savings. At the same time, we do not believe that any legislation that would be tantamount to price controls is in the best interests of the American public. Such controls would be contrary to the principles of the free market, as evidenced by the current movement of many countries away from price controls and central planning and toward a market-based economy.

Finally, in the rush to achieve savings, we must not lose sight of the overriding objective to provide equal access to the best advances in modern medicine to all people, regardless of the method of payment for health care services.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Ingram follows:]

Glaxo
Glaxo Inc.

Statement of
Robert A. Ingram
Executive Vice President
Glaxo Inc.
Before the
Subcommittee on Health and the Environment
House Energy and Commerce Committee
September 14, 1990

Thank you, Mr. Chairman and Members of the Subcommittee.

My name is Robert A. Ingram. I am an executive vice president for Glaxo Inc.

Glaxo Inc. is a United States pharmaceutical company that has its headquarters, research and development and manufacturing facilities in North Carolina. Glaxo employs more than 4,000 people and ranks among the three largest pharmaceutical manufacturers in the United States based on pharmaceutical sales. Glaxo concentrates exclusively on prescription medicines. Among our best known products are Zantac® (ranitidine hydrochloride), an anti-ulcer medication; Ventolin® (albuterol), an anti-asthma bronchodialator; Fortaz® (ceftazidime for injection), an injectable antibiotic; Ceftin® (cefuroxime axetil), an antibiotic for oral use, and Trandate® (labetalol hydrochloride), for treatment of hypertension.

I appreciate this opportunity to discuss Glaxo Inc.'s discount proposal that is designed to make pharmaceutical products available to Medicaid beneficiaries.

Glaxo shares with other pharmaceutical manufacturers the conviction that all Americans should have equal access to the most effective drug products developed by medical science. We also are keenly aware that in many states, the poor of this country do not have the benefit of the most advanced medicines because fiscal constraints have resulted in restrictions on the availability of many medications. We are deeply concerned that cost pressures may lead to further restricted access in the future.

Glaxo has devoted considerable effort to finding ways that we as a pharmaceutical manufacturer can assist in alleviating the financial burdens on Medicaid and assuring access to medicines for the poor. We are here today because we are willing to provide the Medicaid system with significant cost savings.

Glaxo Inc. proposes to give to Medicaid the best discount on single-source pharmaceutical products that we offer to any nongovernmental entity that does not take physical delivery of our products; that is, the managed care industry. We have offered our discount program to every state that provides a drug benefit to Medicaid beneficiaries and have entered into contracts with a number of state Medicaid agencies to provide those agencies with the economic benefits of price competition in the managed care market. We are in the process of negotiating several such contracts. Glaxo believes that its market-based discount program takes advantage of marketplace dynamics to assure consistent savings to Medicaid both now and in years to come.

The "Best Price" Is Not a Realistic or Reasonable Reference Price for the Medicaid Discount.

Before explaining Glaxo's proposal, I want first to explain why the so-called "best price" offered by pharmaceutical manufacturers to any customer, although an appealing phrase, is not a reasonable reference for discounts. Although the "best price" may be reasonable for a few companies, we believe for the industry as a whole, it is not a fair standard. For most manufacturers, the "best price" is the price provided to the Department of Veterans Affairs (DVA). Discounts to that market segment are a historical anomaly that has evolved from World War II efforts to bolster the government's access to needed medicines. Prices in that market have remained artificially low in part because companies like Glaxo have found it reasonable to give the veterans a break in a very small portion of our business. That segment represents only 1 or 2 percent of the total U.S. pharmaceutical market. Moreover, our prices to the DVA depot system are low because the federal government takes delivery and assumes responsibility for warehousing and distribution.

While some pharmaceutical companies' prices to the DVA are close to their commercial prices, for many manufacturers including Glaxo, the federal prices are dramatically lower than prices we quote to any commercial customer. Testimony provided to the Senate Special Committee on Aging last year suggests that Glaxo is not alone in providing the DVA with deep discounts. Discounts listed on the federal supply schedule, for example, according to a staff report of the Senate Special Committee on Aging, range from 41 to 67 percent off the average wholesale price for single-source drugs and 39 to 93 percent for multi-source drugs. These discounts would not be commercially reasonable for a broader segment of the market like Medicaid, which represents between 10 and 15 percent of prescription drug sales.

Companies that have provided generous discounts to the government in the past should not be penalized for doing so. If Medicaid discounts were pegged to the DVA price, companies that offer only small discounts or no discounts at all to the federal government would be rewarded. By contrast, those companies that over the years have offered deep discounts to the DVA would be greatly disadvantaged. The result would be uneven and extremely unfair. Any legislation designed to ensure cost savings to Medicaid should affect each company equally. Glaxo believes that a discount based on a commercial discount to managed care organizations that do not take delivery of pharmaceutical products would be the most equitable and fair means to achieve this result.

Glaxo Offers a Market Based Proposal Designed to Preserve the Competitive Marketplace While Providing Significant Savings to Medicaid.

Historically, third party payers have not been a significant factor in the pharmaceutical market. In recent years, managed care has become a growing and increasingly important competitive influence in the health care sector of the United States economy. The products of virtually every pharmaceutical company are sold in the managed care market at competitive prices set by the aggressive buying power of this growing sector.

In the managed care industry, services are received by beneficiaries from health care providers and are paid for by a third party that contracts with providers. As a third party payer that reimburses for services of providers, the Medicaid system resembles managed care arrangements, such as network model and independent practice association model HMOs and preferred provider organizations. Managed care arrangements are the most analogous commercial customers to Medicaid for pharmaceutical manufacturers.

Glaxo's proposal is designed to provide Medicaid with the same level of discounts achieved in the managed care market by entities that are most like Medicaid in structure. Glaxo has offered to give to Medicaid agencies the best discount we give to those managed health care organizations that, like Medicaid, reimburse for prescription drugs dispensed by pharmacies to participants in the managed care program. Under the Glaxo proposal, each state Medicaid agency would receive a discount from the manufacturer based on the number of units of a specific drug dispensed by pharmacies to Medicaid beneficiaries. In return, the states would be prohibited from imposing restrictions on beneficiaries' access to that manufacturer's products.

The Glaxo proposal gives state Medicaid agencies the benefit of the discounts obtained in the managed care market. Because this market is substantial and growing, it is highly successful in achieving competitive contracts with manufacturers. Some single Independent Practice Association model HMOs, for example, are larger even than California's Medi-Cal, the largest state Medicaid program. In view of the continuing development of the managed care industry, Glaxo believes that as a proxy for Medicaid programs managed care organizations will obtain significant discounts for the states without creating the need for additional federal or state administration to negotiate prices.

Glaxo's discount proposal, because it is referenced to contracts with the managed care industry, makes it difficult for manufacturers to withdraw or raise prices to Medicaid in future years. Discounts for the managed care industry are assured by contracts of several years duration. The most competitive managed care organization will get the best discounts lasting for three to five years. Because those discounts are the reference for Medicaid contracts, we expect that discounts to Medicaid agencies would be assured until a more competitive managed care organization succeeds in getting an even better discount.

We propose that the states remain free to use formularies and prior approval requirements for products whose manufacturers do not offer discounts to Medicaid agencies. Thus, while skeptics claim that manufacturers may withdraw these "voluntary" discounts in future years, withdrawal would subject the manufacturer to the risk of losing a sizeable portion of its business when the state excluded the drug from its formulary. In this way the state would retain considerable leverage to induce manufacturers to offer discounts.

The Forces of the Marketplace Offer Significant Savings for Medicaid.

Our proposal could result in significant savings for Medicaid. Our discounts in the managed care market range from 5 to 20 percent on some products. A fair assumption is that the market as a whole would yield an average discount on Glaxo products of approximately 15 percent. Our proposal does not add administrative costs to Medicaid. Any cost increase resulting from our proposal derives from the access-enhancing requirement that manufacturers' discounts be matched by states' guarantees that beneficiaries will have access to all discounted drugs.

A discount referenced to contracts with the managed care industry would provide savings to Medicaid agencies without distorting the incentives for innovation provided by the free market. Manufacturers depend upon the market system to reward the most innovative and effective products and to determine which products offer clinical advantages over existing products. Because our proposal allows the commercial market to set the discount levels for Medicaid, competition and the incentives for innovation provided by the free market would be preserved.

The Federal Government Should Set Guidelines for Savings by the States.

Increasing numbers of states have achieved significant savings to Medicaid this year by successfully contracting with manufacturers. As stated above, Glaxo is entering into contracts with state Medicaid programs that will result in significant savings to the states and to the federal government. Moreover, we understand that the states are having considerable success in achieving cost savings for Medicaid in contracts with manufacturers besides Glaxo. According to news reports, at least 11 companies are currently negotiating with states. These companies produce many of the most significant therapeutic advances in medicine in the world today. Because there is so much activity in the states, federal legislation may not be necessary at all at this time.

Glaxo believes that the goal of cost savings to Medicaid could be most appropriately achieved through our discount proposal. However, we recognize the difficulty Congress faces in choosing among the various proposals. Given the level of activity by the private sector and the states, federal legislation may not be necessary, at least at this time. Congress has already performed the extremely important job of calling the problem of Medicaid costs to the attention of the pharmaceutical industry. Glaxo and others have responded.

At this point, the wise course is for Congress to continue to harness the energies and the diversity of the private sector and the 50 states -- and not to impose from above a confining formula that would stifle creative efforts to solve the problem.

Thus, we suggest that Congress issue a broad legislative directive to the states to achieve savings in the state drug budgets during the coming year. Such a directive would allow each state Medicaid agency to achieve savings in ways most appropriate to the individual state. Each state could be directed by federal legislation to demonstrate the amount of its savings to the federal government. Such a federally directed mandate would be entirely consistent with the premise of Medicaid that the federal government establish guidelines to be implemented by the states in keeping with the circumstances and particular needs of each individual state.

A final concern is that federal legislation might not preserve the existing contracts between states and pharmaceutical manufacturers. These contracts have been negotiated with the states in good faith and should not be upset by a subsequent federal law. Should Congress pass federal legislation, that legislation should include a "grandfather clause" that would preserve any existing contracts with manufacturers that contribute to overall savings to Medicaid.

As stated above, Glaxo favors providing the Medicaid system with significant cost savings. At the same time, we do not believe that any legislation that would be tantamount to price controls is in the best interests of the American public. Such controls would be contrary to the principles of the free market and may inhibit the discovery of new and important medicines by the research-based pharmaceutical industry.

In keeping with the fundamental principle of Medicaid as a health care reimbursement system for America's poor, again we maintain that any discounts the states obtain from manufacturers must be linked to assurances that physicians will be able to determine when a particular medicine is appropriate for medical care and to prescribe that medicine without restriction. In the rush to achieve savings, we must not lose sight of the overriding objective to provide equal access to the best advances in modern medicine to all people regardless of the method of payment for health care services.

Mr. Waxman. Thank you, Mr. Ingram.

Mr. Ziegler.

STATEMENT OF RONALD L. ZIEGLER

Mr. Ziegler. I am pleased to appear on behalf of America's chain drug stores and those supermarkets and mass merchandising retailers that operate pharmacies, and who are also valued members of NACDS.

Senator Pryor and Representatives Wyden and Cooper are to be commended for the time, thoughtfulness and understanding they have devoted to the issues surrounding prescription drugs and Medicaid cost.

Together, NACDS members operate 40 percent of America's drug stores, and dispense 60 percent of all prescriptions. NACDS has long supported manufacturer rebates. Both Senator Pryor's bill, S. 3029, and the Wyden and Cooper bill include a rebate program that provides meaningful savings to Medicaid, and equally important, assure access to all needed prescription drugs. We support that.

In addition, I want to emphasize that retail pharmacy has contributed significantly to cost containment over the past 8 years. For example, in 1989 alone, retail pharmacy lost $305 million, or 8 percent on dispensing Medicaid prescriptions.

America's drug stores can have an additional impact on cost containment if sensible programs are designed to improve the dispensing and the use of prescription drugs. In order to help do this successfully, the current arbitrary reimbursement system and the way it is being managed by the Health Care Financing Administration simply must be reformed as proposed in Senator Pryor's original Medicaid cost containment bill, S. 2605. Our written testimony discusses this point fully.

This is our position on the drug use review: We support and favor the approach taken in the Wyden-Cooper bill. It is less prescriptive. We support counseling, but we oppose regulations that instruct the pharmacist in strict terms how they should talk to and counsel with their patients.

We are, however, in full support of two major provisions contained in Senator Pryor's new bill and that are not contained in the Wyden-Cooper bill. Both focus on concerns about HCFA's management of the Medicaid prescription drug program.

The first pharmacy reimbursement reform provision in the Pryor bill that we support would require that the dispensing fee used to calculate pharmacy reimbursement in each State be based on a cost study.

The other pharmacy reimbursement reform provision we support would impose a 2-year moratorium on further reductions to pharmacy reimbursement.

We have fully documented our support and concerns in our written testimony.

Mr. Chairman, as an example of the 390 calculations recently made by HCFA to establish the pharmacy reimbursement upper limits for multisource drugs, only 155 were from published sources, a clear, open violation of HCFA's own regulations.

Seventy-seven percent of these were derived from one small labeling company operating with 25 employees out of a small 50,000 square foot warehouse. A 2-year moratorium on reimbursement levels would provide time for full and sound consideration of a sensible pharmacy reimbursement policy.

We ask the committee, as an important first step, to take the uncomplicated action of including the reimbursement provisions contained in Senator Pryor's new bill in any budget package developed by the House this year.

The reforms we support are cost-effective, will save money and will be in the best interest of the Medicaid program and America's low income citizens.

Thank you very much for allowing us to testify, and, Mr. Chairman, my compliments and appreciation to you and your committee for the fine work you are doing to improve health care for all Americans.

[Testimony resumes on p. 688.]

[The prepared statement and attachments of Mr. Ziegler follow:]

Testimony of Ronald L. Ziegler, President and Chief Executive Officer, National Association of Chain Drug Stores

Good afternoon Mr. Chairman and distinguished committee members. My name is Ronald L. Ziegler and I am the President and Chief Executive Officer of the National Association of Chain Drug Stores. I appreciate the opportunity to testify before you today on behalf of the chain drug store industry, and the many supermarkets and mass merchandising retailers that operate pharmacies within their stores and who are valued members of NACDS. A chain drug store as defined by the U.S. Department of Labor includes companies operating four or more pharmacies. These drug stores provide pharmaceutical care to millions of Americans in communities across America. They dispense 60 percent of the outpatient prescriptions in the United States through more than 26,000 drug stores.

NACDS recognizes and agrees that the federal budget circumstances necessitate efficient management and cost containment in all federal programs. The Medicaid program, and specifically the Medicaid prescription drug benefit, is not exempt from the pressure brought on by the budget deficit with which you have the task of addressing.

EXPENDITURE INCREASES IN PRESCRIPTION DRUGS

Expenditures for prescription drugs have increased at a faster rate than the average medical inflation rate. There are a number of reasons for this increase: (1) increased utilization of prescription drugs due to more beneficiaries, higher utilization per beneficiary, and the availability of drug therapy to treat diseases for which no drug therapy was previously available; (2) more effective and higher cost drug products and therapies replacing older, less expensive therapies; and (3) pharmaceutical manufacturer price inflation.

One factor that has not contributed to the increase is Medicaid reimbursement to retail pharmacy. Since 1984, payments to retail pharmacy have decreased from 31 percent to 25 percent of program expenditures, while manufacturer drug products have increased from 65 percent to 71 percent of program expenditures. This change in expenditures is due in part to cost containment imposed on retail pharmacy and in part to manufacturer price increases. The result of cost containment has been to produce an average loss of 8 percent to retail pharmacy on its Medicaid business. In 1989 alone this translated into a shortfall of $305 million.

While increased expenditures for prescription drugs are a concern, they also should be viewed as a positive sign for the Medicaid program as a whole. Even expensive drug therapies have proven to be a financial bargain when compared with other courses of therapy that may involve multiple physician visits and even hospitalization. These increases in prescription drug program expenditures have to some extent been offset by decreased expenditures in other parts of the Medicaid program such as physician fees and hospital payments.

However, even with the recognition of the important cost containment role that pharmaceutical products and services have played in overall medical costs, budget realities necessitate further savings. The reality is that it is simply time for manufacturers to make a contribution to Medicaid budget savings by participating in a meaningful rebate or discount program. Some manufacturers, have recognized their social responsibility in this area and have stepped forward voluntaruy with meaningful rebate programs. While NACDS applauds these manufacturers, and the market in which they operate, NACDS believes that Congressional action is needed to assure full, uniform, and meaningful participation of all manufacturers.

RETAIL PHARMACY IS NOT THE CAUSE OF INCREASED MEDICAID EXPENDITURES

Mr. Chairman, as you are well aware, cost containment efforts are not new to the Medicaid prescription drug program. These efforts have been almost exclusively directed at retail pharmacy, which ironically has not been the source of price inflation. As a result, these past cost containment efforts have done little to curtail the growth rate in Medicaid expenditures because they have not addressed the true causes of the problem which are: (1) manufacturer drug product costs, (2) beneficiary utilization, and (3) the dispensing incentives built into the reimbursement system.

It is for these reasons that the chain drug store industry supports two areas for change in the Medicaid prescription drug program: (1) a credible and viable program of pharmaceutical manufacturer rebates; and (2) a change in the system used to cap payments to retail pharmacies, which should be linked to a cost effective and properly administered drug utilization review program linked to on-line claims adjudication and review. Chain drugs stores have been the industry leader in implementing automated systems and fully support efforts to move in this direction for the Medicaid program. Our position is clearly and concisely outlined in Appendix I of this testimony.

Relative to the first of these two areas, pharmaceutical manufacturer rebates, NACDS has been a long time supporter of rebate programs that result in meaningful savings to the Medicaid program. While rebates can be structured in many ways, we believe meaningful rebates can be achieved without therapeutic substitution or interchange, without price regulation (but anchored to produce meaningful savings), and with access for Medicaid patients to all needed prescription drugs. These concepts are embodied in the rebate program NACDS members helped enact in California this year.

HCFA MANAGEMENT OF THE MEDICAID PRESCRIPTION DRUG PROGRAM

Mr. Chairman, we would be remiss if we did not share with you NACDS's concerns regarding the Health Care Financing Administration's management of the Medicaid prescription drug program. HCFA's management is having a significant negative impact on both Medicaid expenditures and on pharmacy providers.

Dispensing Fees: The first area that we would like to bring to your attention Mr. Chairman is related to the dispensing fees used to set the cap for reimbursement to pharmacy providers. HCFA's regulations specify that a state Medicaid plan must provide for a ''reasonable'' dispensing fee. In the accompanying Appendix II, we have provided you with a list of the current dispensing fees used by the individual state Medicaid programs. As you can see from this list, there is great variation among the state dispensing fees. While the cost to a pharmacy to dispense a prescription does vary somewhat geographically, the extent of the variation and the lack of geographic consistency found in the current fee structure speak to the unreasonableness of HCFA's oversight.

To put these fees in context for you and the committee, a recent scientific study completed by the Pharmaceutical Economics Research Center at Purdue University determined the average cost of dispensing a prescription to be $5.46. This amount is in line with the fees paid in both Texas and Arkansas both of which use a study to establish the Medicaid dispensing fee.

Unreasonable fees are in a large part responsible for the fact that retail pharmacies loses, on the average, 8 percent on its Medicaid business. This amounted to a $305 million loss to retail pharmacy in 1989. This 8 percent figure is not mine, Mr. Chairman, it is based on Congressional Budget Office [CBO] estimates, and the research conducted by Purdue University's Pharmaceutical Economics Research Center. This point is further documented in the NACDS Fact Sheet which is part of Appendix III.

Before we offer potential solutions to these problems, Mr. Chairman, we need to give you another example of how HCFA's management is hurting beneficiaries, providers, and the program itself.

Reimbursement Limits on Multisource Drugs Discourages Generic Dispensing: HCFA has managed to create the only prescription drug coverage program in the country that provides an incentive to dispense higher cost, brand name multiple source drugs instead of chemically identical, ''A'' rated, and less expensive generic products. Other third party prescription drug programs, and the competitive market itself produce prices that provide an incentive for pharmacists to save patients and payers money by the safe and effective use of generic drug products.

The HCFA reimbursement system has come about through arbitrarily set federal caps for the reimbursement of multiple source products. According to HCFA regulations, the federal caps are to be based on the lowest published price for a generic product, regardless of the manufacturer or labeler's ability to supply products to retailers. HCFA has recently published a new list of federal caps for multisource drugs which was effective on September 1, 1990. Upon receiving the list of new caps, the staff of NACDS analyzed the source of the prices used to establish the caps. This analysis is presented in Appendix IV.

Appendix IV places a spotlight on some very interesting facts regarding how HCFA has set the new caps. First of all, 235, well over half, of the new limits were set based on special analyses and not on published prices -- a clear violation of HCFA's own regulations. Secondly, of the 155 caps which were based on published prices as the regulation mandates, over three quarters were based on the published direct price of one small labeler, Qualitest, located in Huntsville, Alabama. Another significant percentage of these prices were based on the company Pharmafair, which has had its entire product line removed from the market by the Food and Drug Administration on two separate occasions. Another company, Pharmaceutical Basics has been subject to both Congressional and criminal investigation resulting in the conviction of several corporate officials. Mr. Chairman, I am sure you will agree that this is no way to manage a prescription drug benefit, nor is it good public policy.

A PLAN OF ACTION

A great deal of thought has already gone into how these problems should be addressed, both by the pharmacy community and by the staff of Senator Pryor's Special Committee on Aging.

This situation allows NACDS to appear here today to support reforms that will have a significant positive impact on both the Medicaid program and on the industry I represent. These reforms can be structured to save the Medicaid program money. In other words, We are not asking for more money for pharmacy providers; but we are asking for your help in correcting problems in the management of the Medicaid prescription drug program.

For some time now, Senator Pryor has recognized the problems with the current HCFA management of the Medicaid prescription drug program. This spring, after months of work with a number of interested parties, including retail pharmacy, Senator Pryor introduced Senate Bill 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990. S2605 contained a change in pharmacy reimbursement caps from the current cost plus fee caps used to regulate pharmacy prices to caps based on the prices set in the competitive marketplace. He included provisions designed to correct the incentives in the current system relative to generic products. This was a simple, workable proposal. While this reimbursement change in its totality was estimated by CBO to produce savings for the Medicaid program as shown in Appendix V, state Medicaid directors were uncomfortable with such a fundamental reform and urged Senator Pryor to change his bill.

Although we are told his support for such fundamental reimbursement reform in the Medicaid program has not waned, Senator Pryor is expected to introduce another bill that will, in part, address the problems we have outlined here today, but is more compatible with the budget reconciliation process than S2605. The elements of Senator Pryor's new reimbursement proposal taken in their totality will also produce significant savings for the Medicaid program.

The proposal includes provisions that would mandate state

Medicaid programs to use a scientific study of the cost of dispensing a prescription in their state to set the dispensing fees used to set reimbursement-caps under their program. It places a moratorium on further arbitrary reductions in the ingredient cost component of reimbursement caps for a period of two years. This moratorium period would provide time for a thorough review of the current reimbursement system and the disincentives it provides for the cost effective dispensing of prescription drugs.

Finally, regarding drug use review, chain drug stores have long been in the forefront of using computers to enhance pharmacy practice. Computer-based claims management systems that verify eligibility and provide information about patient prescription drug use can be effective cost containment tools. Review programs designed to examine physician prescribing and pharmacist dispensing behavior, can if they are not intrusive, enhance the quality of health care and improve patient outcomes. NACDS members are solidly behind these kinds of programs.

On the other hand, requirements that mandate how and when a pharmacist must communicate with patients are intrusive, unnecessary and should not be mandated by the Medicaid program. According to a recent study reported by Ray Gosselin, Editor of Pharmacy Times magazine, at the recent NACDS Pharmaceutical Conference, only 22 percent of all patients need any form of counseling regarding their prescription drugs. NACDS and its members believe that federal mandates designed to regulate the practice of pharmacy are ill advised, are not cost effective, and are not appropriate for inclusion in a budget resolution. I regret that at the time that this testimony was prepared NACDS did not have access to the full text of either Senator Pryor’s new proposal or Congressmen Wyden’s and Cooper’s proposal. NACDS would like to reserve the right to submit to the Committee our comments regarding these legislative proposals at a later date.

Mr. Chairman, I thank you once again for the opportunity to testify here before you and would be happy to answer any questions that you may have.

APPENDIX I

NACDS POSITION
ON
MEDICAID PRESCRIPTION DRUG PROGRAM CHANGES

The Congress and the Administration are considering, for inclusion in the 1991 federal budget, a number of proposals designed to reduce Medicaid prescription drug expenditures. Many of these involve provisions originally included in Senator Pryor's recently introduced Pharmaceutical Access and Prudent Purchasing Act of 1990 (S 2605). **NACDS has given careful consideration to the various proposals under consideration and urge that the Congress not act in piecemeal fashion, but rather, consider all aspects of the Medicaid program in making the budget decision, including:**

(1) the cost of drug products to the program;

(2) the utilization of prescription drugs by the Medicaid beneficiaries; and

(3) the program's reimbursement to retail pharmacies.

As summarized here, and detailed in the accompanying Fact Sheet, retail pharmacy has borne the brunt of Medicaid cost containment for the past 6 years. These cost containment measures have resulted in a system of reimbursement that produces an average loss of 8 percent on retail pharmacy's Medicaid business, according to the Congressional Budget Office (CBO) and other estimates. In 1989, this amounted to $305 million in losses to retail pharmacies.

NACDS believes that it is appropriate that the Congress focus on the root cause of increased Medicaid expenditures, namely drug product costs and increased utilization. At the same time, the enactment of manufacturer rebate and drug utilization programs alone will do little to prevent further and arbitrary reductions in reimbursement to retail pharmacy by Medicaid administrators.

As outlined below, the reimbursement changes we are proposing would replace the current regulated payment caps with caps based on competitively established prices. The proposal is budget neutral in the short term but in the long term, as the rate of generic dispensing increases, it will reduce Medicaid expenditures, and when combined with drug utilization review, produces significant immediate savings.

In proposing these reimbursement changes, we are not seeking to increase the aggregate reimbursement amount going to retail pharmacy, but rather, to replace the current arbitrarily established reimbursement caps with ones that are based on a predictable competitive marketplace.

NACDS SUPPORTS THE ENACTMENT OF THE FOLLOWING PACKAGE OF CHANGES TO THE MEDICAID PROGRAM:

1) A PROGRAM OF MANUFACTURER REBATES that produces legitimate savings. Manufacturer rebates are a standard business practice which is not generally available to the Medicaid program. Rebates take many different forms and NACDS will support a rebate program that will produce meaningful savings to the Medicaid program. The details of the program should be worked out between the pharmaceutical manufacturers and the Congress.

2) A DRUG UTILIZATION REVIEW PROGRAM that will enhance patient care through improved prescribing and dispensing of prescription drug products and which will bring about better patient compliance and understanding of their drug therapy.

   - The program should be designed to detect improper prescribing and dispensing and educate physicians and pharmacists about their prescribing and dispensing behavior.

   - The program should not be so prescriptive as to restrict the ability of pharmacists to exercise their professional judgement when communicating and consulting with individual patients.

   - Drug utilization review should be supported by standardized computer-based claims adjudication systems.

   - **NACDS supports drug utilization review because it will benefit the Medicaid program and its beneficiaries. However, it must be understood that the implementation will increase a retail pharmacy's operating costs and reduce its revenues because fewer prescriptions will be dispensed.** DUR may also reduce expenditures in other parts of the Medicaid program.

3) REPLACING THE CURRENT REGULATED, FEE-BASED REIMBURSEMENT SYSTEM FOR PRESCRIPTION DRUGS WITH ONE BASED ON COMPETITIVELY ESTABLISHED PRICES. Manufacturer rebates and drug utilization review programs need to be linked to a change in Medicaid reimbursement.

   A. Reason for the change in reimbursement:

   The current Medicaid payments to retail pharmacy are capped using published wholesale prices [e.g. average wholesale price (AWP)] plus a dispensing fee. For example, the maximum allowable payment for Drug X might be $16.00 (AWP=$13.00 + a dispensing fee of $3.00). Published wholesale prices are considered by some today to be an inappropriate benchmark for reimbursement purposes. This perception has resulted in:

(1) Arbitrary state-by-state reductions in the wholesale price (e.g. AWP) component of the reimbursement cap. Reductions amount to as much as 12 percent.

(2) Arbitrary suppression of dispensing fee increases. Current dispensing fees range from \$2.60 - \$6.25, with the average being \$3.68. It costs a chain drug store pharmacy an average of \$5.46 to fill a prescription, including pharmacist and administrative salaries, computer costs, and overhead [*An Assessment of Chain Pharmacies' Costs of Dispensing a Third Party Prescription*, Pharmaceutical Economics Research Center, Purdue University, May 1990].

(3) Losses to retail pharmacies on their Medicaid business averaging eight percent (8%). This amounted to a total loss of \$305 million to retail pharmacy in 1989. Since net profits in retail pharmacies are estimated to be in the 2-4 percent range, some pharmacies are forced to increase their prices to other patients in order to continue to serve the prescription and health care needs of Medicaid beneficiaries.

B. **NACDS proposes to replace this regulatory-based reimbursement system with one based on real competitively established market-based prices in each state.** The plan has the following features:

- Retail pharmacies would be reimbursed by each state program their usual and customary charge to the general public.
- Medicaid would be protected from paying high prices because reimbursement for single source, generic multi-source, and restricted brand name multi-source prescriptions will be capped at the 90th percentile of the usual and customary charges. This means that 10 percent of the charges will be reduced and 90 percent will be paid as billed.
- Reimbursement for non-restricted brand name multi-source drugs would be capped at the 70th percentile of pharmacy charges. This lower limit is designed to encourage the increased dispensing of multi-source generic drugs which are generally less costly than brand name multi-source drugs.
- The reimbursement caps would be updated monthly based on the previous month's billings to a state for a drug.
- Pharmacy charges would be subject to audit with appropriate remedies applicable. Actual charges to the Medicaid would be compared with charges to the general public.
- Pharmacy practice acts in all states would be changed so as to require physicians to indicate in their own handwriting that a brand name multi-source drug was "medically necessary" in order for it to be dispensed.

C. Effect of a Market-Based Reimbursement System on the Medicaid Program

- **It will not produce windfall profits for America's drug stores.** Based on CBO estimates, as explained in the NACDS Fact Sheet, the change in reimbursement caps will be budget neutral with the probability of producing savings.

  (1) For single source drugs, the current Medicaid cap is, on the average, slightly below the 90th percentile of usual and customary charges. Therefore, changing the cap will have little effect on Medicaid expenditures for single source drugs.

  (2) For generic drugs, the current Medicaid cap is substantially below the 90th percentile and will increase Medicaid expenditures. However, when combined with a 70th percentile cap on non-restricted brand name multiple source drugs, the net effect will produce a slight reduction in Medicaid expenditures because it will increase the dispensing of generic drug products. Not withstanding the recent problem with generic drug manufacturers, the appropriate dispensing of generic drugs has been an important part of reducing the cost of prescription drugs for more than 30 years and will be even more important in the future.

- **Medicaid will never pay the highest market-based price.** A 90th percentile cap means that high-end prices will be penalized and reduced. Billings below the cap would be paid as billed.

- **Retail pharmacies will not raise their prices as a result of the 90th percentile cap.** Retail prescription prices benefit from a highly competitive retail market involving over 57,000 pharmacies. Retail pharmacy bills the Medicaid program the same price charged to the general public. Since, on the average, Medicaid represents only 17 percent of a pharmacy's business, raising prices in this competitive market for purposes of maximizing Medicaid reimbursement would cause a loss of other business.

- **The 90th percentile cap will be less inflationary to Medicaid than the current AWP-based caps.** AWP amounts are set by manufacturers and are not always based on competitive considerations. As explained in the Fact Sheet, retail prices are competitively set and lag behind AWP increases.

- **A MARKET-BASED REIMBURSEMENT SYSTEM IS GOOD FOR BOTH MEDICAID AND RETAIL PHARMACY.**

APPENDIX II

STATE MEDICAID DISPENSING FEE

State	Dispensing Fee	State	Dispensing Fee
Arizona	$2.50	Tennessee	$3.91
New York	2.60	Nevada	3.95
West Virginia	2.75	Indiana	4.00
Pennsylvania	2.75	Louisiana	4.00
Nebraska	2.89-5.05	California	4.05
Missouri	3.15	South Carolina	4.05
Ohio	3.23	Massachusetts	4.06
Washington	3.24-4.33	Colorado	4.08
Kentucky	3.25	Minnesota	4.10
New Hampshire	3.25-3.65	Wyoming	4.16
Maine	3.35	Florida	4.23
Rhode Island	3.40	North Carolina	4.24
Virginia	3.40	D.C.	4.25
Alaska	3.45-7.90	Montana	4.25
Connecticut	3.55	South Dakota	4.25
Illinois	3.58	Idaho	4.30
Delaware	3.65	Georgia	4.41
New Mexico	3.65	Hawaii	4.67
Utah	3.65	Wisconsin	4.69-6.67 (for unit dose)
Oregon	3.67-4.02	Maryland	4.78-4.80
Michigan	3.72	Mississippi	4.91
New Jersey	3.73-4.07	Oklahoma	5.00
Alabama	3.75	Texas	[(EAC + 4.26)/.970] EAC
North Dakota	3.75	Arkansas	4.16 + (0.093 x EAC)
Vermont	3.75	Iowa	6.25
Kansas	3.75-6.10		

Prepared by the National Association of Chain Drug Stores - 9/10/90

APPENDIX III

FACT SHEET

MEDICAID PRESCRIPTION DRUG PROGRAM

Impact Analysis of Manufacturer Rebates, Drug Utilization Review, and Retail Pharmacy Reimbursement(1)

I. RETAIL PHARMACY MARK-UPS FOR THE DISPENSING AND CONSULTATION FUNCTION ARE NOT THE CAUSE OF INCREASED MEDICAID PRESCRIPTION DRUG EXPENDITURES.

Federal Medicaid expenditures for prescription drugs will, according to Congressional Budget Office (CBO) preliminary estimates, amount to $3.0 billion(2) in 1991 and grow to $6.5 billion in 1995. This represents a growth rate that is 2.6 percent greater than the rate for overall Medicaid expenditures. Federal government program savings from $1.5 billion to $2.0 billion are achievable over the next five fiscal years. Two billion dollars over five years represents a savings of about 12%. According to CBO:

> **Drug Product Costs**(3) account for seventy-one percent (71%) of Medicaid program expenditures. Of this seventy-one percent (71%), fifty-five percent (55%) is for brand name and generic multi-source drugs and forty-five (45%) from single source brand name drugs.
>
> **Wholesaler mark-ups** related to the warehousing and distribution of drug products account for four percent (4%) of total Medicaid expenditures.
>
> **Retailer mark-ups**(4) related to the dispensing and patient consultation functions account for the remaining twenty-five percent (25%). These mark-ups have been severely restricted by the caps on pharmacy reimbursement for single and multi-source prescription drugs as administered by HFCA and the state programs. The result of these restrictions has been to reduce average retailer mark-ups since 1984 from thirty-one percent (31%) to twenty-five (25%),(5) and to reduce Medicaid payments to retail pharmacy to below the breakeven point (see section V. below). At the same time both pharmacy operating costs and drug product costs, as explained above, have risen sharply. For example, drug product costs as a percentage of Medicaid expenditures have increased from sixty-five percent (65%) to seventy-one percent (71%) since 1984.

* *Annotations are found in the attached appendix. Readers are encouraged to refer to these annotations when they occur in the text.*

II. DRUG PRODUCT COST INCREASES HAVE RESULTED IN INCREASED MEDICAID EXPENDITURES.

Generic and brand name multi-source drugs account for 39% of total Medicaid expenditures. Brand name single-source drugs account for 32%. Together they account for 71% of all Medicaid costs. As noted above, this percentage has increased since 1984.

- Hospitals, health maintenance organizations, state and federal agencies including the Department of Veterans Affairs have effectively contained prescription drug costs by obtaining rebates. The Congressional Budget Office estimated that rebates under Senator Pryor's legislative proposal (PAPPA) would amount to twenty-five percent (25%) on single source products, five percent (5%) on multi-source products, and five percent (5%) on over-the-counter medications.

- These same rebates are not generally available to the Medicaid prescription drug program, or to retail pharmacy, although four states have enacted rebate programs for their Medicaid programs.

III. MANUFACTURER REBATES WOULD REDUCE MEDICAID EXPENDITURES.

Manufacturer rebates, or discounts as they are sometimes called, are not a new idea. It is common business practice for manufacturers to rebate a percentage of their sales to certain purchasers, including hospitals, HMO's, and government agencies, such as the Department of Veterans Affairs. Larger discounts are typically more readily available for multi-source than for single source drugs.

- Rebate programs differ in their specifics, but take two general forms:

  (1) **A formula program** in which the purchaser (e.g. Hospital, Insurer, Medicaid) specifies the percentage rebate that is expected. This might be a straight percentage (e.g. 10% rebate on all sales of a product), or a formula based on the percentage differences between a manufacturer's best price to any purchaser and the price offered to retailers. For example, the difference between the Department of Veteran Affairs price and the price offered to retailers might be 10% for a particular drug. This would constitute the amount of the rebate due the Medicaid program.(6)

  (2) **A bid program** differs from a formula program in that the purchaser does not establish the amount of the rebate. Instead, the rebate amount is negotiated between the purchaser and the manufacturer. PAPPA, Senator Pryor's legislative proposal, would require Medicaid programs to negotiate rebates with manufacturers.

- A rebate program, to be effective, requires that restrictions be placed on the prescribing and dispensing of drugs for which a manufacturer does not provide a rebate. Drugs which are available without restriction are considered to constitute a purchaser's (e.g. Hospital, Insurer, Medicaid) formulary. Hence, restricted drugs are non-formulary drugs. Restrictions on a drug may take one of three forms:

  (1) Total exclusion of the drug. In this form, under no circumstances will the purchaser pay for and therefore allow the prescribing and dispensing of the drug.

  (2) Restrictions that require a physician to obtain prior authorization in order to prescribe a non-formulary (restricted) drug. Authorization is usually based on the grounds that the specific drug is required, in the physician's judgement, to be medically necessary.

  (3) Restrictions that require the physician to certify on the prescription that a non-formulary (restrictive) drug is "medically necessary" for a patient. This is less restrictive than prior authorization. PAPPA would permit physicians to prescribe restricted drugs by certifying that a drug was medically necessary.

- Rebates on generics and brand name multi-source drugs are more readily available than rebates for single source drugs because multi-source products are chemically identical and hence substitutable, one for the other.(7) This results in significant price competition among manufacturers of generic multi-source drugs.

- Rebates on single source drugs are less available than rebates on multi-source drugs because single source products are chemically different and are not generally substitutable. As a result, purchasers, such as hospitals and HMO's, often form committees composed of health professionals (e.g. physicians and pharmacists) to determine the extent to which and under what circumstances single source drugs may be interchanged.(8) That is, to the extent that they can be used to treat patients with similar medical conditions. Drugs which are determined to be therapeutically interchangeable are then deemed candidates for rebates and are subject to competitive bidding among manufacturers.

- Therapeutic interchange is the most powerful tool available to purchasers for obtaining rebates on single source products because they compel manufacturers to compete on price. On the other hand, if manufacturers of single source drugs cooperated with a purchaser's rebate program, the establishment of therapeutic interchangeability of products would not be required. Therapeutic interchange does raise one important issue regarding program savings. Since not all single source products may be determined to be interchangeable, program savings based on therapeutic interchange may not be as great as rebates obtained on all single source drugs.

- State Medicaid programs, hospitals, HMO's, and government agencies currently use a variety of mechanisms (e.g. physicians, pharmacists, consultants) to determine the interchangeability of single source products. PAPPA, Senator Pryor's legislative proposal, would establish a National Pharmacy and Therapeutics Committee. The committee would formulate professional and scientific advice regarding the interchangeability of single source products. This information would be used by the state Medicaid programs in negotiating manufacturer rebates.

IV. DRUG UTILIZATION REVIEW IS AN IMPORTANT COST CONTAINMENT TOOL FOR THE MEDICAID PROGRAM.

It would result in a reduction in payments to retail pharmacy amounting to $660 million over 5 years (71% in drug product costs and 29% in wholesale and retail markups associated with the warehousing, distribution, and dispensing of products and the patient counseling functions).

- Savings can be achieved in two ways:

    (1) Through retrospective review of billed claims, physicians and pharmacists are identified for the purpose of correcting inappropriate prescribing and dispensing of prescription drugs.

    (2) Adverse drug interactions are reduced and patient compliance is increased through improved patient information and pharmacist-patient communication and consultation.

- **While the Medicaid program and its beneficiaries will benefit from the implementation of a drug utilization program, it must be understood that the implementation will increase a retail pharmacy's operating costs and reduce its revenues because fewer prescriptions will be dispensed.** Current reimbursement caps do not recognize these added costs to the pharmacy. However, a 90th percentile cap based on competitive market-pricing would more adequately support an expanded role for the American pharmacist. DUR may also reduce expenditures in other parts of the Medicaid program.

- In order to minimize the cost of utilization review to retail pharmacy and the Medicaid program, it is important that pharmacists continue to exercise their professional judgement in deciding when and how to communicate with a patient. Legislative requirements demanding that pharmacists consult or communicate with each and every patient when in their professional judgement such interactions are not needed, would be equivalent to dictating that a physician must follow fixed legislated rules when dealing with a patient in every situation and circumstance. In addition to being inappropriate and unnecessary, such prescriptive legislation is costly.

V. MEDICAID PAYMENTS TO RETAIL PHARMACY HAVE BEEN REDUCED TO BELOW THE BREAK EVEN POINT.

As noted above, retailer mark-ups amount to only twenty-five percent (25%) of total Medicaid expenditures. To simply cover the cost of dispensing a Medicaid prescription, a mark-up of thirty-three percent (33%) is required(9). This means that retail pharmacy is on average losing eight percent (8%), (33%-25%), on prescriptions dispensed to Medicaid beneficiaries(10). Stated another way, it costs a retail pharmacy an average of $5.46 to fill a prescription and Medicaid only reimburses a retail pharmacy on the average $4.05 for its dispensing and patient consultation functions.(11) **In 1989, this loss amounted to an estimated $305 million.**

- Revenue from the Medicaid program is a significant part of a retail drug store's business, amounting on the average to seventeen to eighteen percent (17-18%) of prescription drug sales. Net profits for retail pharmacies are estimated to be in the two to four percent (2-4%) range. Therefore, underpayments by the Medicaid program have a significant affect on the American drug store's bottom line, to the point that in some cases it can make a difference between whether a drug store stays in business or not.

- Inadequate reimbursement from the Medicaid program has forced some pharmacies to increase their prices to other patients in order to continue to serve the prescription and health care needs of Medicaid beneficiaries. Retail pharmacy is socially bound to dispense Medicaid prescriptions and thus is forced to cost-shift to other market segments. The ability of retail pharmacy to cost-shift has reached its limit.

- The shortfall to retail pharmacy resulting from Medicaid reimbursement is largely due to the extremely low caps that are applied to pharmacy billings for generic products.(12) These restrictions on generic products are counter productive because they serve as a disincentive for pharmacists to dispense generic drugs and for pharmacists to encourage physicians to prescribe generic drugs.

NOTE: It is assumed by many that a pharmacy is paid the Average Wholesale Price (AWP) for a drug plus a dispensing fee. **THIS IS INCORRECT.**

(1) *For single source drugs,(13) each state Medicaid program establishes a reimbursement cap based on the sum of an estimate of a pharmacy's acquisitions cost (e.g. AWP-10%) plus a dispensing fee (e.g. $3.68). A pharmacy bills the Medicaid program the same amount that it charges to the general public. Pharmacy charges to Medicaid that are below the reimbursement cap are paid at the amount that is billed. Pharmacy charges above the reimbursement cap are reduced and paid at an amount equal to the cap. Most of the charges above the reimbursement cap are reduced and paid at an amount equal to the cap. Most of the charges billed to Medicaid for single source drugs are below the established cap and thus, the drug store is paid the amount they charge to the general public as determined by competitive market factors.*

(2) *For multi-source brand name and generic products,*(14) *the federal government (HCFA) establishes a reimbursement cap for each drug based on the lowest published AWP price for the generic and brand name equivalent*(15)*. This amount is multiplied by 150% and a dispensing fee is added to it in order to establish the cap. Just as with single source drugs, a pharmacy bills the Medicaid program the same amount it charges the general public. Charges below the reimbursement cap are paid the same amount as billed. Charges above the cap are reduced and paid at an amount equal to the cap. The same cap applies to the generic and brand name multi-source products, unless the physician specifies that the brand name drug is medically necessary, in which case the higher single source cap is applied to the brand name drug. Because the caps on multi-source drugs are so low, fifty percent (50%) of the billings for multi-source drugs are reduced to the lower payment amount established by the cap, resulting in prescriptions in many cases being dispensed by America's drug stores as less than the cost of doing business.*

VI. A CHANGE IN MEDICAID REIMBURSEMENT FOR PRESCRIPTION DRUGS IS NEEDED AND MUST BE LINKED TO THE IMPLEMENTATION OF MANUFACTURERS REBATE AND DRUG UTILIZATION REVIEW PROGRAMS.

NACDS proposes to replace the current regulatory-based reimbursement system with one based on real competitively established market-based prices in each state. The plan has the following features:

- Retail pharmacies would be reimbursed by each state program their usual and customary charge to the general public. Pharmacies could not establish "special" Medicaid prices.

- Medicaid would be protected from paying high prices because reimbursement for single source, generic multi-source, and restricted brand name multi-source prescriptions would be capped at the 90th percentile of the usual and customary charges. This means that 10 percent of the charges would be reduced and 90 percent would be paid as billed.(16)

- Reimbursement for non-restricted brand name multi-source drugs would be capped at the 70th percentile of pharmacy charges. This lower limit is designed to encourage the increased dispensing of multi-source generic drugs which are generally less costly than brand name multi-source drugs.

- The reimbursement caps would be updated monthly based on the previous month's billings to a state for a drug.

- Pharmacy charges would be subject to audit with appropriate remedies applicable.

- Pharmacy practice acts in all states would be changed so as to require physicians to indicate in their own handwriting that a brand name multi-source drug was "medically necessary" in order for it to be dispensed.

Effect of a Market-Based Reimbursement System on the Medicaid Program

- **It will not produce windfall profits for America's drug stores.** Based on CBO estimates, the change in reimbursement caps will be budget neutral or possibly even produce savings.

  (1) For single source drugs, the current Medicaid cap is, on the average, slightly below the 90th percentile of usual and customary charges. Therefore, changing the cap will have little effect on Medicaid expenditures for single source drugs.

  (2) For generic drugs, the current Medicaid cap is substantially below the 90th percentile and will increase Medicaid expenditures. However, when combined with a 70th percentile cap on non-restricted brand name multiple source drugs, the net effect will produce a slight reduction in Medicaid expenditures because it will increase the dispensing of generic drug products.(17) Not withstanding the recent problem with generic drug manufacturers, the appropriate dispensing of generic drugs has been an important part of reducing the cost of prescription drugs for more than 30 years and will be even more important in the future.

- **Medicaid will never pay the highest market-based price.** A 90th percentile cap means that high-end prices will be penalized and reduced. Billings below the cap would be paid as billed.

- **Retail pharmacies will not raise their prices as a result of the 90th percentile cap.** Retail prescription prices benefit from a highly competitive retail market involving over 57,000 pharmacies. Retail pharmacy bills the Medicaid program the same price charged to the general public. Since, on the average, Medicaid represents only 17 percent of a pharmacy's business, raising prices in this competitive market for purposes of maximizing Medicaid reimbursement would cause a loss of other business.

- **The 90th percentile cap will be less inflationary to Medicaid than the current AWP-based caps.** Many people associated with the Medicaid program incorrectly assume that a reimbursement cap based on the 90th percentile would be inflationary. This is incorrect because the current caps increase as manufacturer AWP prices increase. AWP amounts are set by manufacturers and are not always based on competitive considerations. On the other hand, experience has shown retail price increases lag behind manufacturer price increases, therefore caps based on retail prices will inflate slower than ones based on manufacturer (AWP) prices.(18)

- **A market-based reimbursement system is good for both Medicaid and retail pharmacy.** Changing the reimbursement cap for generic drugs to the 90th percentile, combined with enhanced generic dispensing, would increase average pharmacy mark-ups in the Medicaid program to a level more consistent with the cost of dispensing a Medicaid prescription.(19)

APPENDIX

(1) All statistics included in this FACT SHEET are derived from the July 27, 1990 preliminary Congressional Budget Office (CBO) estimate of S 2605 as amended by staff, unless otherwise noted. Senate Bill 2605 was introduced by Senator David Pryor's and is known as the Pharmaceutical Access and Prudent Purchasing Act of 1990.

(2) $3.0 billion dollars represents the federal share of Medicaid expenditures in 1991 based on CBO estimates. Total program expenditures, state and federal, would amount to about $5.0 billion dollars in 1991. These amounts are exclusive of administrative expenses.

(3) Drug product cost is the price retailers pay to manufacturers and wholesalers for drugs dispensed to the Medicaid population. The manufacturer prices include the costs of manufacturing, marketing, research, and profit.

(4) Retailer mark-ups are commonly referred to as gross margin. They are the amount added to the cost of drug products in order to cover the costs associated with dispensing a drug. They include: pharmacist and administrative salaries, computer costs, overhead, and bad debt - and any profit.

(5) Research conducted by SysteMetrics/McGraw Hill, *Pharmaceutical and Health Care Expenditures in Medi-Cal, 1984 - 1989*, February 5, 1990, estimated the proportion of Medicaid expenditures accounted for by the retail pharmacy dispensing and consulting functions to have fallen 6 percentage points from 1984 to 1989 (39% to 33%). Adjustments for the researchers' misunderstanding of the current Medicaid reimbursement system and applying the trend nationally results in a change from 1984 to 1989 of 31% to 25%.

(6) A rebate program can be constructed so that it applies to a manufacturer's entire product line. The Merck Sharp & Dohme program uses this approach. On the other hand, a rebate can be based on individual drug products. The four state Medicaid rebate programs and most other purchasers currently employ this second approach.

(7) Generic drugs that are "A" rated by the Food and Drug Administration have been determined to be chemically identical and to have the same therapeutic effect as the originator brand name drug. Generic drugs with less than an "A" rating may not in all circumstances produce the same therapeutic effect as the originator brand name drug.

Fact Sheet prepared by the following NACDS officials: Randy L. Teach, Senior Vice President for Health Policy and former U.S. Department of Health and Human Services official; Leonard DeMino, Vice President, Pharmacy Affairs and former Vice President for Operations Peoples Drug Stores; and Kurt A. Proctor, Ph.D. - Pharmacy Administration, Director of Research and Information.

(8) Systematic research has not been conducted on the therapeutic interchangeability of single source drugs. However, it is unlikely that single source drugs, even if they are determined to be interchangeable in some circumstances, can be as readily substituted as in the case of "A" rated generic drugs.

(9) The National Pharmaceutical Council's, *Pharmaceutical Benefits Under State Medical Assistance Programs*, September 1990 (in print), estimates the Average Medicaid prescription is reimbursed at $16.18. This amount is significantly below the average price of $18.80 (*Drug Topics*, February, 1990) for all prescriptions. This difference is largely due to the reimbursement caps employed by the Medicaid program. It costs chain drug stores (amount not available for independent pharmacies) $5.46 to fill a prescription ($6.39 for third party prescriptions), according to the Pharmaceutical Economics Research Center at Purdue University as reported in *An Assessment of Chain Pharmacies' Costs of Dispensing a Third Party Prescription*, May 1990. Therefore, on the average, a 33% mark-up ($5.46/$16.18 = 33%) is required for a pharmacy to break-even when filling a Medicaid prescription.

(10) DHHS research, *Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered by Medicare*, May 1989, estimates the retail pharmacy mark-up to be 32%. If this high-end figure is used instead of the 25% estimate, retail pharmacy is then, on the average, about breaking even on its Medicaid business ($5.46/16.18 = 33%).

(11) The average retail mark-up of 25 percent equates to a dollar gross margin of $4.05 ($16.18 × .25 = $4.05). The difference between the actual cost of dispensing a prescription, $5.46, and this dollar gross margin is $1.41 ($5.46 – $4.05) which represents an 8 percent loss per prescription ($1.41/$16.18).

(12) Based on an analysis of over 17 million actual prescriptions from PDS's June 1990 database, NACDS estimates that 50% of all claims for multi-source drugs are reduced by the current Medicaid caps on reimbursement.

(13) A single source drug is a drug marketed or sold by only one manufacturer, usually under a proprietary name. These are usually brand name drugs which are under patent protection. For purposes of Medicaid, single source drugs are classified as "other drugs" and are subject to the same reimbursement as multi-source drugs that do not meet the Medicaid criteria or for which a physician has certified that a specific multi-source brand name drug is medically necessary.

(14) A multi-source drug is a drug that is marketed or sold by two or more manufacturers or labelers, or a drug marketed or sold by the same manufacturer or labeler under two or more proprietary names, or both under a proprietary name and without such a name. Multi-source drugs typically include an originator brand name drug for which the patent has expired and its generic equivalents. For purposes of Medicaid, only multi-source drugs which are approved by the Food and Drug Administration, and classified as category "A," and available from at least three suppliers are reimbursed as a multi-source drug.

(15) The lowest price for a multi-source drug is obtained from one of three sources. Data published in the *Red Book* microfiche, the First Data Bank analysis (*Blue Book*), and the *Generic Buying and Reimbursement Guide* published by Medi-Span and other Medi-Span analyses. The listed price for package sizes of 100 units is used, or if the drug is not commonly available in quantities of 100, the package size commonly listed is used.

(16) The 90th percentile cap means the top 10% of pharmacy billings would be reduced to the amount that is equal to the price at which 90 percent of charges to the general public fall below. Pharmacy billings below this cap (90% of the billings) would be paid as billed to the Medicaid program. PAPPA, as amended by the Senate Special Committee on Aging staff, provides a very strong incentive for pharmacists to substitute generic drugs for multi-source brand name drugs because for multi-source brand name drugs a pharmacy would only be paid up to a 70th percentile cap instead of the 90th percentile cap that would be in effect for generic and single source drugs.

(17) This conclusion is based on analyses by Lee Strandberg, Ph.D. Oregon State University on 1984-1990 data from Pharmacists' Service Group which employs a 90th percentile cap on reimbursement for the third party prescription drug programs that it manages.

(18) PAPPA, as amended by the Senate Special Committee on Aging staff provides a very strong incentive for pharmacists to substitute generic drugs for multi-source brand name drugs because for multi-source brand name drugs a pharmacy would only be paid up to a 70th percentile cap instead of the 90th percentile cap that would be in effect for generic and single source drugs.

(19) Generic drug prices are significantly lower than brand name multi-source prices. However, retail pharmacy generally makes a higher percent margin on generic drugs than on brand-name drugs. Therefore, while increased generic drug dispensing will lower Medicaid payments to retail pharmacy in the aggregate, a 90th percentile cap would result in higher aggregate margins for retail pharmacy. This would bring Medicaid reimbursement more in line with the actual cost of dispensing a prescription.

The Truth About
Medicaid Reimbursement to America's Pharmacies

The points below correct some fundamental misunderstandings about the current Medicaid reimbursement system that have been based on a study conducted for the Pharmaceutical Manufacturers Association (PMA) by **SysteMetrics/McGraw-Hill** on the California Medicaid program.[1] Organizations, such as PMA, who are opposed to the pharmaceutical manufacturer rebate provisions of Senator Pryor's bill S 2605 have focused attention on other provisions of the bill to divert attention from the rebate provisions. One element of S 2605 would change the caps on reimbursement to America's drug stores from the current regulated system to one based on the highly competitive retail prescription marketplace. Questions regarding the merit of such a change largely have been based on the results of this study which utilized a number of incorrect assumptions about Medicaid reimbursement.

MYTH: The dispensing and patient consultation functions carried out in retail pharmacies account for 33 percent of Medicaid prescription drug expenditures.

FACT-1: According to Congressional Budget Office (CBO) estimates, retail pharmacy's dispensing and patient consultation functions account for 25 percent of Medicaid prescription drug expenditures.[2]

The SysteMetrics Medi-Cal study made a number of incorrect assumptions to arrive at their 33 percent figure:

1) The first incorrect assumption was that the cap to reimbursement for all products in California was set at the average wholesale price (AWP) plus a dispensing fee. While this is correct for single source drugs, the cap for multiple source drug products is based on federal financial participation (FFP) limits which are significantly below the AWP-based caps. This would account for some of the difference between the SysteMetrics figure and CBO's.

2) The second incorrect assumption was that retail pharmacies are always reimbursed at the reimbursement cap. Federal regulations require that retail pharmacies be paid the lower of the usual and customary price paid by the general public or the reimbursement cap. NACDS analyses show that most prescriptions are paid at the usual and customary charge which is below the cap. This misinterpretation accounts for a majority of the difference between the SysteMetrics and CBO data.

FACT-2: The percentage of Medicaid prescription drug expenditures accounted for by retail pharmacy's dispensing and patient counseling functions has decreased 6 percentage points since 1984.

Not withstanding its use of incorrect assumptions, the SysteMetrics study does support the conclusion that retail pharmacy's share of Medicaid prescription drug expenditures has and continues to decline. This trend also is supported by other data. This reduction is due in large part to the severe restrictions on Medicaid payments to retail pharmacies that have been put in place by state Medicaid programs.

MYTH: **Retail pharmacies are experiencing windfall profits from the Medicaid program.**

FACT: **On the average, retail pharmacies are losing 8 percent on their Medicaid business. This amounted to an estimated $305 million in losses to retail pharmacy in 1989 alone.**

Research conducted by the Pharmaceutical Economics Research Center at Purdue University has shown that, on the average, it costs a retail pharmacy $5.46 to dispense a prescription.[3] Based on the CBO estimate of retail pharmacy's 25 percent share of Medicaid expenditures and the National Pharmaceutical Council's reported average Medicaid reimbursement per prescription of $16.18, a retail pharmacy averages a dollar gross margin of $4.05 per Medicaid prescription ($16.18 × .25).[4] This means that a pharmacy is losing $1.41 per Medicaid prescription ($5.46 — $4.05), or over 8 percent ($1.41/$16.18). If a pharmacy's entire business was dependent on Medicaid, it would be out of business.

[1] "Pharmaceutical and Health Care Expenditures in Medi-Cal 1984-1989: Final Report," SysteMetrics/McGraw-Hill Inc., Santa Barbara, California, April 10, 1990.

[2] Preliminary Cost Estimate of S 2605 as amended by staff, Congressional Budget Office

[3] *An Assessment of Chain Pharmacies' Costs of Dispensing a Third Party Prescription*, Pharmaceutical Economics Research Center, Purdue University, West Lafayette, Indiana, May 1990.

[4] *Pharmaceutical Benefits Under State Medical Assistance Programs*, (in print), National Pharmaceutical Council, Inc., Reston, Virginia, September 1990.

APPENDIX IV

MEDICAID REIMBURSEMENT LIMITS
FOR
MULTI-SOURCE DRUGS

SUMMARY OF FINDINGS

- In many instances, price information used to establish reimbursement lists is not available to the general public. Of the 390 reimbursement limits, only 155 are from published sources that can be obtained by the retail pharmacist.

- HCFA uses manufacturer direct prices instead of Average Whole Prices to establish reimbursement limits. Purchasing at direct prices means that the retailer performs the wholesale functions. This cost is *not* reflected in the Medicaid reimbursement formula.

- Published direct prices may not be readily available to retailers. An analysis of the 155 published prices indicates 77% are derived from a single company. This company has 25 employees and a 50,000 square foot warehouse. Other companies used by HCFA to establish the reimbursement limit have had, on various occasions, their product lines recalled by the FDA.

- The limits do not reflect current prices. They are 6 - 18 months old. Therefore, retail pharmacy directly absorbs the cost of inflation and manufacturing price increases.

- HCFA does not verify either the accuracy or availability of the prices and products of the companies used to establish the reimbursement limits.

MEDICAID REIMBURSEMENT LIMITS FOR MULTI-SOURCE DRUGS

HCFA establishes the Medicaid reimbursement limits for multi-source drugs used by the state Medicaid agencies for making payments to prescription drugs. The limits are calculated by adding to the agencies dispensing fee, a product cost that is equal to lowest advertised price for a drug multiplied by 150%. [dispensing fee + (lowest published drug price x 150%)]. The Health Care Financing Administration (HCFA) has established reimbursement limits for 390 of the most commonly prescribed multi-source brand name and generic drugs. These mandated limits are used by state Medicaid agencies to pay retail pharmacies for dispensing prescriptions to Medicaid beneficiaries.

Price information for calculating the reimbursement limits which will take affect on 9/1/90 were derived from four sources (according to HCFA's publication "Payment for Services - Addendum A"):

1) February 1990 special Medi-Span Analysis;
2) The "Generic Buying Guide of Medi-Span - 2nd quarter 1990",
3) The January 1990 Red Book; and
4) A January 1990 special First Data Bank (Blue Book) analysis.

A wide range of information is listed in these sources for each drug product. (See the attached summary table.)

From the listed advertised prices, HCFA selects the lowest price among the AWP and the Direct Prices for a drug for purposes of establishing its reimbursement limit. This **lowest price is always the direct price.** There are a number of serious concerns raised by this HCFA policy.

1) HCFA has used price information not available to pharmacies in establishing its reimbursement limits. This is inconsistent with HCFA's regulations regarding prescription drug reimbursement (Sec. 447.33216) which requires that reimbursement limits are to be established using the *"published prices for the least costly therapeutic equivalent (using all available national compendia)."*

    - 215 of the 390 reimbursement limits were calculated from an analysis prepared in January 1990 ***exclusively*** for HCFA by First Data Bank.

- 20 of the 390 reimbursement limits were calculated from an analysis prepared in February 1990 ***exclusively*** for HCFA by Medi-Span.

- Reimbursement limits for the remainder of the products, totalling 155, were calculated from published Medi-Span and Red Book data from January 1990.

2) Direct Prices are established by manufacturers. These prices are not appropriate for establishing Medicaid reimbursement limits. Purchasing directly from a manufacturer usually involves substantial added cost to retailers related to the warehousing, repackaging, and distribution of products. These wholesaling costs are not reflected in the manufacturers direct prices and not reimbursed by Medicaid.

3) **The published prices are not readily available to retailers.** An analysis of the 155 published prices that are publicly available reveals that Medicaid reimbursement limits are being established by small and possibly unreliable suppliers. Listed below are companies and the percentage of times that the company's direct price was used by HCFA to establish the Medicaid reimbursement limit.

Company	NO.	%
Qualitest Products Inc.	119	76.8%
Pharmafair, Inc.	22	14.2%
Regal	2	1.3%
Pharmaceutical Basics	2	1.3%
Best Generics	2	1.3%
Bolar Pharm. Co.	1	.65%
Bioline Labs, Inc.	1	.65%
Genetco, Inc.	1	.65%
Gen-King	1	.65%
J.J. Balan	1	.65%
Richlyn	1	.65%
Vangard Labs	1	.65%
Warner Chilcott	1	.65%
TOTALS	155	100.1%

4) **The reimbursement limits are not based on current pricing data.** Pharmaceutical prices at the manufacturer and wholesale level have risen faster than the CPI. The HCFA reimbursement limits which will be effective September 1, 1990 are based on Jan./Feb., 1990 price information. This means that retail pharmacy will absorb the effects of 6 to 18 months of inflation - assuming the reimbursement limits will be in effect from Sept. 1990 to Sept. 1991.

5) HCFA does not verify:

- the accuracy of the advertised prices;
- the availability of the advertised prices;
- the ability of manufacturer to supply the product at advertised price under terms acceptable to retail pharmacy.

Please see attached Manufacturer/Supplier Profile.

MANUFACTURER/SUPPLIER PROFILE

As noted in the Analysis, of the 155 product reimbursement limits, 77 percent are derived from a single, non-manufacturing company, Qualitest Products, Inc. of Huntsville, Alabama. Company supplied information details the activities of Qualitest's 25 employer and 50,000 square foot warehouse.

The reliance by HCFA upon the prices offered by a non-manufacturing company is inherently suspect. Since generic and brand multi-source drugs constitute 55 percent of the $3 billion federal Medicaid expenditures, it is highly questionable whether a single non-manufacturing company can be the basis for reimbursement. It goes without saying that no reasonable expectation can be established to suggest that Qualitest possesses the necessary product to supply the demand for multi-source products. In actuality, Qualitest is nothing more than a private-labeler that seeks pharmaceutical product to fulfill created demand.

NACDS also objects to the policy which encourages the use by HCFA of a single nonmanufacturing company to establish reimbursement limits. No assurance can be provided of uninterrupted supply of product. Furthermore, as a labeler, Qualitest relies on a source of supply that it can not guarantee either in terms of quality or quantity.

Additionally by the reimbursement system includes to two companies (Pharmafair and Pharmaceutical basics) that have been implicated in the recent generic drug controversy and a supplier that is no longer a going concern. Taken together with Qualitest, Pharmafair, Inc.; Pharmaceutical Basics; and Regal constitute 94 percent of the published prices available to pharmacist.

As mentioned, NACDS is very concerned with recent events implicating Pharmaceutical Basics and Pharmafair Pharmaceutical Basics was the subject of both a Congressional investigation and action by the U.S. Attorney which resulted in product recalls and criminal convictions of corporate officers. Pharmafair has had a long listing of manufacturing problems and on more than one occasion has ceased production of its entire product time. Finally, Regal has for all practical purposes ceased operations.

Based on this information, it is reasonable to include that retail pharmacy is confronted with a reimbursement system for multi-source drugs that is based upon suspect sources and out-dated information. It is well documented that HCFA's has little interest in and does not verify the following:

- the accuracy of the advertised prices;
- the availability of the advocated prices; and
- the reliability of the supplier or manufacturer to supply product at advertised prices.

NACDS suggest that the Medicaid reimbursement limits for multi-source drugs is part of a system that is ill-conceived, unreliable, and fails to meet any standard of fairness.

MEDI-SPAN®
GENERIC BUYING AND REIMBURSEMENT GUIDE

GLOSSARY OF TERMS

Generic Equivalence Code (GEQ) indicates the FDA therapeutic equivalence evaluation as published in *Approved Prescription Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). Codes beginning in "A" indicate that products are evaluated to be therapeutically equivalent to other pharmaceutically equivalent products. Products coded "B" are not considered by the FDA to be equivalent.

GEQ Codes shown in **BOLD** type are taken directly from the "Orange Book" listing of approved NDA holders. GEQ codes listed in *ITALICS* have been determined by Medi-Span from other sources.

Name of generic ingredient(s) and form.

Strength of each ingredient.

Package quantity.

The current **Direct Price** from the manufacturer.

The **Average Wholesale Price** currently being charged by wholesalers as calculated and verified by Medi-Span.

Alphabetical listing of generic manufacturer condensed names. Reference products are listed in italics. See page 5 for complete listing.

WARFARIN SODIUM TAB
5 MG

100 EA		GEQ	DP	AWP
ABBOTT	00074-7210-01	**BX**	19.49	23.14
BEST GENER	54274-0234-10	*AB*	8.35	12.50
BEST GENER	54274-0100-10		5 30	7 88
BIOLINE	00719-1993-10	*BX*	5.99	10.50
BOLAR	00725-0045-01	**BX**		7 88
CONSOL MID	00223-2377-01			8.75
DIXONSHANE	17236-0424-01	*AB*		14 11
DUPONT	00056-0172-70	**AB**		33.30
GENETCO	00302-8204-01	*BX*		7 65
GLENLAWN	00580-1408-01	*BX*		9 84
GOLDLINE	00182-1522-01	*BX*	6 99	10.50
H L MOORE	00839-6628-06	*BX*		12.08
HARBER	51432-0902-03			14.50
INTERSTATE	00814-8522-14			10 50
JJ BALAN	00304-0921-01			7.04
LANNETT	00527-1003-01			10 35
LEMMON	00093-0145-01	*AB*		16 42
MAJOR	00904-2562-60	*BX*		13.70
MARTEC	52555-0005-01	*AB*		15 98
PARMED	00349-8391-01	*AB*		10 38
PHARM BASI	00832-0627-00	**AB**		12.50
RUGBY	00536-4853-01	*BX*		7 81
SCHEIN	00364-0640-01	*AB*		16.80
URL	00677-0794-01	*BX*		15 80

AAWP = 12.03 GEAP = 14.10

AAWP is the average of all AWPs for each generic drug in a given category, not including the reference, or branded, drug.

Generic Equivalents Average Price (GEAP) is the average of AWPs for all generic products coded "A" (therapeutically equivalent), not including reference drugs. When a generic entity has no approved equivalent or the quantity is insufficient to calculate an average, the GEAP will indicate "n/a".

HCFA FFP (not shown in this example) refers to the Federal Financial Participation (FFP) limits for certain therapeutically equivalent multiple source drugs as defined in the Health Care Financing Administration (HCFA) *Medicaid Manual*. The FFP limit replaces the former Federal Maximum Allowable Cost (MAC) ceilings (which expired October 29, 1987) that were administered by the Pharmaceutical Reimbursement Board of the U.S. Department of Health and Human Services. The actual implementation and use of the FFP limits are dependent on the policies set forth in the individual state medicaid programs. The FFP limit sizes referenced in the GBRG correspond to sizes referenced in the HCFA *Medicaid Manual*.

OTHER TERMS:

Reference Products are considered branded pharmaceuticals, or industry standards, determined to represent the original manufacturer of a drug, or a distributor through a cross-licensing agreement. These manufacturers' names are in italics.

Drug Efficacy Study Implementation (DESI) findings that a particular drug is considered "less than effective" by the U.S. Government are indicated with an * to the left of the NDC number.

Labeler Codes are the first five digits of the NDC number, which is listed to the right of the manufacturer name.

APPENDIX V

Savings/Cost Estimates of the Retail Pharmacy Provisions of Senator Pryor's Bill - S. 2605

The figures below represent the savings/cost estimates of the retail pharmacy provisions of Senator Pryor's bill S. 2605 as amended by the staff of the Senate Special Committee on Aging. These provisions are: 1) replace the system used to cap pharmacy providers' reimbursement with one based on the 90th percentile of marketplace prices; 2) a complimentary reimbursement cap change for innovator multiple source products that when combined with the other reimbursement cap change would result in savings through encouraging the use of less expensive generic equivalents; and 3) a drug utilization review (DUR) program tied to a computerized claims management system.

As shown in the table below, the net result of the reimbursement cap changes is a $83 million savings to the Medicaid program over five years. The DUR program would contribute an additional $557 million in savings when tied to the electronic claims management system.

Five Year Savings/Cost Estimates
(all estimates in millions of dollars)

S. 2605 Provision	1991	1992	1993	1994	1995	Total
1. Change in Reimbursement	0	0	72	82	93	247
2. Generic Encouragement	-15	-40	-65	-100	-110	-330
3. DUR	-15	-78	-119	-165	-180	-557
Total	**-30**	**-118**	**-112**	**-183**	**-197**	**-640**

Donald Muse

Estimates by Donald N. Muse, Ph.D.
September 12, 1990

Savings/Cost Estimates of the Retail Pharmacy Provisions of Senator Pryor's New Bill (Pryor II)

The figures below represent the savings/cost estimates of the retail pharmacy provisions of Senator Pryor's new bill, sometimes referred to as Pryor II. These estimates are based on draft legislative language provided to the estimator by NACDS and may not reflect the actual bill submitted. The provisions estimated are: 1) a "set-aside" of a percentage of the manufacturers' rebates to be returned to pharmacists as restitution; 2) a moratorium on further reductions in the caps to pharmacy provider reimbursement; 3) a requirement for state Medicaid programs to base dispensing fees on a study of the cost to dispense a prescription; 4) an audit of retail pharmacies to ensure compliance with state pharmacy regulations related to generic dispensing; and 5) a drug utilization review (DUR) program tied to a computerized claims management system.

As shown in the table below, the net result of the pharmacy provider reimbursement and audit provisions (Items 2, 3, and 4) is a $106 million savings to the Medicaid program over five years. As in Senator Pryor's first bill, S. 2605, the DUR program would contribute an additional $557 million in savings when tied to the electronic claims management system.

Five Year Savings/Cost Estimates
(all estimates in millions of dollars)

Pryor II Provision	1991	1992	1993	1994	1995	Total
1. Pharmacist Restitution	0	2	22	38	0	62
2. Cost Moratorium	0	0	0	0	0	0
3. Dispensing Fees	0	0	0	61	63	124
4. Generic Encouragement	-10	-45	-50	-60	-65	-230
5. DUR	-15	-78	-119	-165	-180	-557
Total	**-25**	**-121**	**-147**	**-126**	**-182**	**-601**

Donald Muse

Estimates by Donald N. Muse, Ph.D.
September 12, 1990

Mr. **Waxman**. Thank you, Mr. Ziegler.

Mr. Rector.

STATEMENT OF JOHN M. RECTOR

Mr. **Rector**. Thank you, Mr. Chairman, on behalf of the independent pharmacies and the 75,000 pharmacies that practice their profession in the pharmacies we represent. We are certainly pleased to be here today to offer our support for the Wyden-Cooper legislation introduced on Wednesday.

We are especially interested in equitable cost containment amendments that recognize the actual source of the escalating cost of the outpatient prescription drug program and that provide the program equal access to manufacturer prices now available generally to Medicare and other nonprofit entities, including those servicing indigents.

It is a far broader scope of low pricing then the Veterans' Administration prices that were just recently, moments ago, alluded to.

The scandalous reality is although Medicaid serves exclusively indigent persons, market forces have denied access to the prices available to other comparable programs which receive the best price.

We, too, support the Senate legislation, which has enjoyed, as I am certain the Cooper and Wyden legislation, strong bipartisan support and consumer support. It is because it is basic equal access for Americans, including indigent persons, it is the right thing to do.

Several States, in anticipation of this action by Congress, have passed enabling legislation. For example, in the first bill signed by Governor Wilder in Virginia, one of the first acts he signed to become law was the Medicaid equal access law.

On the point of reimbursement, pharmacy—of course, beneficiaries have been the victims of the lack of access to the pricing that is available to comparable entities. We have been subjected since the outset in the Medicaid program to an extensive, elaborate, increasingly unfair scheme of price controls, and our comments in the record do elaborate on price controls as they have been in the Medicaid program for the past several decades.

In our market, there is a wide range of prices that have been established for the same product. They are special prices. It is very important if we can make any one point as thoroughly as another, we would like to make the point these prices are not based on economies of scale or whether a purchaser takes possession of drugs.

The prices we are talking about are nonprofit prices. There are special Federal laws going back to the thirties that exempts price discrimination so companies that make as much sales are not violating Federal law. There has been case law to include public schools, public libraries.

The well-known Utah case, the Logan case, where it was extended to reach the purchase of a bowling alley and bowling alley supplies by the Utah State University. The scope and exception is quite broad.

Medicaid is prototypical of the nonprofits intended by that exception to antitrust price discrimination. We believe the Wyden-Cooper legislation provides the basic equity necessary to remedy the shortfall.

We have had a second class program for Medicaid recipients because we have had first class prices for Medicaid while comparable programs have enjoyed equal access to nonprofit pricing. We have submitted extensive comments in our record as to what the opposition of this worthy idea have engaged in.

I will not elaborate on those, but suffice it to say the opposition has focused on virtually everything that the Pryor legislation and that now the Wyden-Cooper legislation is not—and I have submitted on behalf of our organization extensive observations on that point.

There has to be an equitable, fair hammer. As we indicated market prices left to their own, without these prices, legislation, and debate about it has stimulated it.

Enactment of legislation will ensure it. We need the carrot. We need the hammer. The point is it could have been a loss in special tax credits. We have wondered throughout this recent discussion—I am certain in the next coming days on the discussion of Wyden-Cooper which certainly, we are heartened to learn Ms. Collins has supported.

The question is often asked, why is there so much opposition to the equity of this in the Medicaid and poverty program getting the prices to which they are entitled? We have concluded really the real concern is the concern this justifiable step may be in fact a first step towards achieving price equity for prescription drugs in the general private marketplace. We certainly hope that it will be.

Thank you very much.

[The prepared statement of Mr. Rector follows:]

Prepared Statement of John M. Rector, Vice President of Government Affairs and General Counsel, National Association of Retail Druggists

Mr. Chairman and members of the subcommittee, I am John M. Rector. I serve as Vice President of Government Affairs and General Counsel for the National Association of Retail Druggists.

The National Association of Retail Druggists [NARD] represents the owners of 40,000 independent pharmacies, where over 75,000 pharmacists dispense more than 70 percent of the nation's prescription drugs. Together, they serve 18 million persons daily and provide nearly 85 percent of the Medicaid pharmaceutical services. NARD has long been acknowledged as the sole advocate for this vital component of the free enterprise system.

NARD members are primarily family businesses. We have roots in America's communities. The neighborhood independent druggist typifies the reliability, stability, yet adventuresomeness that has made our country great.

We appreciate the opportunity to appear before the Subcommittee to express our support for sound Medicaid budget initiatives. We are especially interested in equitable cost containment amendments that recognize the actual source of the escalating costs of the outpatient prescription drug program and that provide the program equal access to manufacturer prices now available generally to Medicaid and to other nonprofit entities, including those serving indigents. The scandalous reality is that although Medicaid serves exclusively indigent persons, Medicaid has been denied access to the prices available for other comparable programs and entities that receive the "best" price. Instead of a first class program with equal access to prices for comparable entities, we have first class prices and second class programs.

We have supported as our top legislative priority this year the "Pharmaceutical Access and Prudent Purchasing Act," S. 2605, introduced by Senator David Pryor, Chairman of the Senate Special Committee on Aging. Medicaid equal access to prescription drug prices for indigents is the centerpiece of S. 2605. The basic equity of this long overdue approach enjoys wide support among consumer groups and especially those interested in the wellbeing of Medicaid recipients. The bill also enjoys strong bipartisan cosponsorship. The cosponsors include Senators Kerrey, Lott, Breaux, Baucus, Jeffords, Burdick, Exon, Conrad, Johnston, Bumpers, Adams and Kohl. Senate Majority Leader Mitchell told our annual Legislative Conference on May 7, 1990 of his support for this legislation. Health and Human Services Secretary Sullivan informed Senator Harkin as chairman of the Appropriations Subcommittee on the Labor, Health and Human Services, Education, and Related Agencies, earlier this year, that such legislation could help provide states the leverage they needed to obtain the lowest prices. The Merck Sharp and Dohme Corporation offered state Medicaid programs its best price and pledged to limit price increases to the CPI. In June, the White House agreed with Senator Pryor and his allies that manufacturer prices are an appropriate target for Medicaid cost containment to be addressed in the Budget Summit. And more recently, other major pharmaceutical corporations have offered best price approaches.

We have strongly supported the efforts of the Budget Summit to provide Medicaid with equal access to pricing. Our best intelligence leads us to conclude that virtually all states are eager to negotiate equal access pricing. Several states, in anticipation of Congressional action, have enacted their own enabling legislation.

One of the first bills signed by Virginia's Governor Douglas Wilder was a Medicaid equal access bill. Additionally, the Maryland legislature has formally petitioned both Houses of Congress to enact equal access for Medicaid.

No one in the hearing room this morning needs to be reminded, however, that there is another point of view. In his remarks to his Senate colleagues on July 25, 1990, "Drug Manufacturers: Making Profits on Backs of Poor," Chairman Pryor explained the activities of our opponents. In summary he characterized their approach as "untrue and insulting". Interestingly, the opponents have focused almost exclusively on what the proposal is not. Although at times their approach has been unpleasant, at best, we are heartened by their collective failure to pose one sound argument in opposition to the actual equal access provisions of the Senate legislation.

Principally, beyond personal attacks on Senator Pryor, they have focused attention on the so-called "or else" clause. This eq the sanction to assure that equal access pricing is made available for Medicaid. Therapeutic exchange was the "or else" in S. 2605; more recently, denial of access to the Medicaid outpatient prescription drug program is the "or else."

Recently, Health and Human Services Secretary Sullivan told the Senate Appropriations Committee in response to a question about what could be done administratively to encourage equal access for Medicaid, in part that ". . . we have been unable to assist the states in overcoming their major problem of the refusal of drug manufacturers to submit bids."

This legislation provides the essential incentive—the "carrot," "hammer," "stick," "sugar"—to assure that the program will not in the future be denied equal access to prescription drug pricing as it has been in the past and is presently. The "or else" could have been a loss of special tax credits. The point is that a sufficient incentive is required to assure equity for Medicaid.

Our opponents have miscast this legislative effort as one that would mandate the "cheapest" prescription drug. The truth is that it will encourage all prescription drugs to be made available at the "cheapest" or "best" price.

Our opponents have argued that the legislation will mandate second class treatment. The truth is that price equity for Medicaid will help assure that Medicaid recipients will have even fuller access to prescription drugs.

Our opponents have argued that the legislation mandates the "or else" provisions. The truth is that, unless there is an industrywide criminal conspiracy not to provide Medicaid equal access, no one could honorably suggest that the "or else" provisions are mandated.

Our opponents have argued that the savings would be insufficient. The truth is that price discrimination so permeates the prescription drug marketplace, and the price discrepancies are so radical when compared to other markets, that assuring Medicaid the "best" price will yield significant savings.

Our opponents have argued that an unnecessary, burdensome, costly new bureaucracy would be required. The truth is that existing marketplace mechanisms, long ago established to provide the best price for nonprofits generally, including those like Medicaid that serve exclusively indigent persons, are already available to deliver price equity for the most eligible "best price" customer: the Medicaid outpatient drug program.

Our opponents have disingenuously claimed that because retail pharmacy pays the "highest price" for prescription drugs Medicaid should pay the "highest price." The truth is that all consumers are entitled to equal access and that discrimination in the general marketplace against retail pharmacy hardly supports continued discrimination against the Medicaid outpatient drug program.

Today we are pleased to support the efforts by Congressmen Ron Wyden and Jim Cooper and others to provide Medicaid equal access. We endorse the "Medicaid Prescription Drug Fair Access and Pricing Act of 1990." We also have endorsed the Senate companion bill, S. 3029, the "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990," introduced September 12, 1990 by Chairman Pryor. Market forces have led to the denial of equal access to fair pricing for the Medicaid outpatient drug program. The indigent persons eligible for this Medicaid benefit are entitled to full pharmaceutical services and products. These bills will help guarantee the Medicaid outpatient prescription drug program equal access to prices established by individual corporations for nonprofit entities, especially those, like Medicaid, that serve exclusively indigent persons. We have no trouble with the notion of "nominal" prices being excluded, so long has there is no tax subsidy beyond the actual cost involved.

Substantial savings in the $3.5 billion outpatient prescription drug program are associated with even modest reductions in the prices available to Medicaid. The Health Care Financing Administration [HCFA] certainly could have achieved price equity for Medicaid through the regulatory process. However, the agency has declined to do so, choosing instead to reduce beneficiary coverage and cut pharmacy reimbursement. These initiatives have had virtually no effect on overall prescription drug prices, but they have contributed to the second class stature of the program. We have had price controls for pharmacists in the Medicaid program since the early 1970's. One interesting development this summer is that our opponents surprisingly announced their support for these price controls, including the most recent unfair lowering of the price control ceiling. Since 1985, all HCFA efforts to ostensibly control prescription drug costs in the Medicaid outpatient program have either assaulted small businesses participating in Medicaid or limited Medicaid beneficiary coverage. It is no coincidence that the leaders of this Congressional effort to assure a first class program for Medicaid recipients are nationally recognized small business advocates. Senator Pryor recently received the Small Business Advocate award from the Small Business Legislative Council, Congressman Wyden chairs the Regulation, Business Opportunities, and Energy Subcommittee of the Small Business Committee, and Congressman Cooper is an active, key member of the Antitrust, Impact of Deregulation and Privatization Subcommittee of the Small Business Committee. They are familiar with our marketplace; they know that the special monopolistic forces in our market have denied equal access to Medicaid and many other purchasers entitled to price equity. Our members, like these Congressional advocates, know that neither HCFA approach addresses the true source of the escalating cost to Medicaid.

We support consumer and Medicaid recipients' efforts for legislation that provides the Medicaid outpatient drug program equal access to manufacturer drug prices now available to Medicaid generally and to other nonprofit entities. We don't know the total percent of Medicaid expenditures for prescription drugs. The outpatient program, which is exclusively for drugs, amounts to 7 percent of the Medicaid program. Each of the largest Medicaid components (ICF—30 percent, Inhospital—27 percent, and SNF—13 percent), however, purchase an undetermined but significant amount of prescription drugs. A wide range of prices have been established for the same product. Special drug prices are available to nonprofits. Such sales are exempt from price discrimination laws. These prices are not based on economies of scale or whether the purchaser takes possession of the drugs. The nonprofit price is the lowest price. For example, a nonprofit entity pays $5 for a patented prescription drug while retail pharmacists and Medicaid currently pay $32. In the extreme, nonprofit entities pay 1 cent while retailers and Medicaid pay a dollar. Our position is that Medicaid, as a pure nonprofit program serving 100 percent indigent persons, is entitled to the lowest nonprofit charity prices established by the manufacturers. As noted, these prices are not based on the volume purchased or other economies of scale, but, in fact, are based on the nonprofit status of the purchasing entity. Special contracts known in our marketplace as "own use" contracts are written for nonprofit sales, but the regular private drug distribution system is used to store and deliver the product.

These marketplace mechanisms are common, inexpensive, not burdensome, and readily available for implementation of equal access for Medicaid. In effect, under the legislation, a state Medicaid program will sign an "own use" contract and receive its "best price" rebates via a chargeback or other well-established mechanism, typically from a drug wholesaler. These business practices are in place in virtually every Congressional district in the country.

The multiple pricing levels for prescription drugs in the United States have been thoroughly documented by this Subcommittee and the Subcommittee on Oversight and Investigations. In our view, most of this pricing conduct is illegal.

A recent Supreme Court decision, *Texaco, Inc.* v. *Hasbrouck,* June 14, 1990, emphasizes that even traditional distinctions in prices between a wholesaler and retailer will be found illegal unless there is a significant value-added aspect to the functional behavior of the wholesaler. This decision serves to highlight the bogus nature of multitier pricing, which provides mail order, drug vendors, nursing homes, HMO's, hospitals, and many other for profit pharmacies significant competitive advantages to the detriment of independent retail pharmacy and consumers.

It is our view that only true charities, such as Medicaid or those otherwise providing uncompensated care, are entitled to discriminatory prices. There is, as mentioned, special treatment in the law for price discrimination to nonprofits. The 1938 Nonprofit Institutions Act (c. 283, 52 Stat 446, May 26, 1938) exempts nonprofit institutions and those selling to them or facilitating the delivery of such sales from the general antitrust sanction for selling at different prices so long as the products are not resold. (In 1988, Congress enacted the Prescription Drug Marketing Act, Public Law 100–293, developed by this Committee, which made such resales serious felonies.) There is disagreement about the scope of the 1938 Act, but all agree that true charities, those serving indigents such as Medicaid, are entitled to obtain the lowest or "best" price. A major organization representing the pharmaceutical industry, for example, told the Senate Special Committee on Aging last summer that "This Act embodies the strong public policy in favor of allowing sellers to provide products at lower prices to charity purchasers."

Thus, there is a special pharmaceutical marketplace for nonprofit entities. To the best of our knowledge, all manufacturers have established the lowest price for this marketplace. These prices are enjoyed by nonprofit entities including hospitals, HMO's, nursing homes, mail order pharmacies, and others that serve few, if any, indigent persons. Basic equity demands that Medicaid have access to this special class of trade. The Wyden-Cooper legislation provides this equity.

Additionally, we support provisions in Chairman Pryor's "Medicaid Anti-Discriminatory Drug Price and Patient Benefit Restoration Act of 1990," S. 3029, drafted in response to the Budget Summit initiatives that will begin to restore the unfair cuts in pharmacy Medicaid reimbursement of recent years. This restitution is achieved by setting aside a modest 10 percent of the rebates associated with equal access for Medicaid. The moratorium we have been seeking on further assaults by HCFA on pharmacy reimbursement reform for pharmacy providers are also included in S. 3029.

Additionally, we support a set aside of a very modest portion of the rebates to underwrite the efforts of investigators and prosecutors to police and otherwise enforce the equal access program.

In summary, we support Medicaid equal access: to provide a fair deal for Medicaid and its beneficiaries; to stop second class treatment; to focus cost containment on the source of Medicaid drug costs and save at least $2 billion over 5 years; to provide to the Medicaid outpatient drug program prices already widely available to other tax-supported and nonprofit programs; and to limit administrative costs by using the time-tested private enterprise system in place today in every state and in every Congressional district.

In closing, we would like to reiterate our strong support for providing equal access to prescription drug pricing in the Medicaid budget initiatives being negotiated by the Budget Summit that will eventually be addressed by both the House of Representatives and the United States Senate.

In the next Congress we look forward to helping to establish significant Medicaid pharmacy reimbursement reform by law, and to making more progress in the broader campaign to guarantee equal access to prescription drug pricing throughout the private marketplace and for independent retail pharmacy customers in particular.

If I have been asked once, I have been asked a 1,000 times: Why is the pharmaceutical industry opposed to equal access pricing for Medicaid?! Certainly, it's not our responsibility to answer this question, but perhaps a May 10, 1990 Washington Post article, by Spencer Rich, entitled "Senator Seeks to Stem Rise in Medicaid Drug Costs," provides some insight to the answer. It read in part as follows: ". . . the Pryor plan is strongly opposed by the Pharmaceutical Manufacturers Association, which sees it as an *opening wedge to cut prices everywhere.* (emphasis added) 'If these misguided policies were adopted at the federal level in Medicaid, you'd see a lot of attempts to move those policies into the private sector,' said the PMA president . . ."

In fact, when Senator Pryor introduced S. 2605, he said to his Senate colleagues, on May 10, 1990: "By now it may be obvious that while the drug companies don't want to negotiate drug prices with Medicaid programs, Medicaid isn't the issue. They are deathly afraid that the rest of the American public, those with workplace and retiree health plans, will be able to get the same deals by using the same negotiating strategy. Or in other words, they are afraid the idea will spread and catch on. Mr. President, I would like my colleagues to think about this for just a moment: when was the last time someone asked us to vote against an idea because it was so good it might catch on?"

We hope that they are right. We hope that it does catch on.

Ultimately, we support legislation to insure equal access for fair prices for retail pharmacy and consequently for the majority of American consumers who are presently victimized by multitier pricing. But for now and for the remainder of the 101st Congress, Second Session, our top priority is the enactment of equal access for Medicaid.

On behalf of the Officers, Executive Committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to participate in the development of Medicaid budget initiatives in response to the Budget Summit.

Mr. WAXMAN. Thank you, Mr. Rector.

Mr. Gans.

STATEMENT OF JOHN A. GANS

Mr. GANS. My name is John Gans. I am the chief executive officer of the American Pharmaceutical Association, the National Professional Society of Pharmacists.

I would apologize to the subcommittee for the lateness of our written testimony. I was out of the country. It is my fault, not my staff's.

Quality patient care is the primary consideration for developing our position on the issues before us today. In the area of drug therapy one only need to look at the record to see the need for a more comprehensive system of providing it.

Today nearly 20 percent of all hospital admissions can be traced in some kind of drug intervention. We support the lengthy initiatives such as H.R. 5589, which seeks to ensure greater access by the Medicaid populations to the full range of prescription medication and quality drug therapy.

We support the need to focus attention on skyrocketing drug costs which have been the result of manufacturers' pricing philosophies. We feel the manufacturers must play a meaningful role.

The Medicaid program should have equal access to the best prices offered to manufacturers to other purchasers of drugs.

I will focus my remarks on two areas of the proposed legislation, drug utilization review and therapeutic interchange.

H.R. 5589 requires States participating in Medicaid to provide for a drug use program. As drug therapy has become increasingly complex and costly, the role of the provider has become central to effective drug use. This role has often been referred to as prospective DUR. It is critical, Mr. Chairman, that this complex aspect of patient care cannot be viewed as the communication of data across the electronic sale device in a pharmacy.

The delivery of pharmacy care to the patient is a series of steps involving patient care application, patient communication and ongoing monitoring and assessment. The literature is replete with studies with document improvements with the quality of therapy which result from the active involvement of the pharmacist, that is why it is critical that efforts to improve the use of drugs in the Medicaid program recognize and support the pharmacists' provision in these clinical services.

H.R. 5589 also calls for a study of therapeutic interchangeability among pharmaceutical products. There has been much confusion on this issue. We advocate therapeutic interchange which is the use of a formulary system or drug list to guide drug therapy and it happens every day in organized health care systems throughout this Nation.

The essential component is a drug list which physicians and pharmacists develop using the best scientific and clinical information available. These formularies are developed locally by joint committees of physicians and pharmacists and they are tailored to conform with local practice standards and to meet the patients' need as they exist in the particular system.

As therapeutic interchange became more widespread in the 1960's through the 1980's there arose among manufacturers an intensive competitive to get through drugs in formularies. That often resulted in a severe discounting of drug prices to VA and other organized health care settings.

Most of you in this room who have received care from a hospital or HMO in the recent years have had your care developed through the formulary process. Now this has moved to the ambulatory care settings.

Therapeutic interchange is not second class care as its critics have claimed. We of the American Pharmaceutical Association fully support therapeutic interchange and we strongly feel that this system can be adapted to Medicaid and will prove to be a significant improvement over the current system so long as physicians and pharmacists, the health practitioners best trained and who are directly involved with the patients under their care, control the process.

In conclusion, Mr. Chairman, we appreciate the opportunity to appear before the subcommittee. Legislation to reform Medicaid's drug pricing policies is needed. We look forward to working with the subcommittee to achieve that objective.

[The prepared statement of Mr. Gans follows:]

Prepared Statement of John Gans, Chief Executive Officer, American Pharmaceutical Association

My name is John Gans, and I am the chief executive officer of the American Pharmaceutical Association, the national professional society of pharmacists. I am pleased to appear before the Subcommittee to address legislation to reform Medicaid drug pricing policies.

APhA represents all areas of pharmacy practice. A guiding principle APhA has followed since our founding in 1852 is to advocate those principles which enable pharmacists to enhance the care of our patients. Quality patient care is the primary consideration for developing our position on the issues before us today. In the area of drug therapy, one only need to look at the record to see the need for a more comprehensive system of providing it. Today, nearly twenty percent of all hospital admissions can be traced to some kind of drug misadventure. It is therefore imperative that any drug program this country undertakes incorporate in it measures that will assure that health care professionals—physicians and pharmacists—work together to assure that the appropriate medication is provided and used properly. That is pharmacy's mission as well.

We commend Congressmen Wyden and Cooper for their efforts in proposing H.R. 5589, the "Medicaid Prescription Drug Fair Access and Pricing Act of 1990." We support legislative initiatives, such as H.R. 5589, which seek to ensure greater access by the Medicaid population to the full range of prescription medications and to quality drug therapy. We support the need to focus attention on skyrocketing prescription drug costs which have principally been the result of manufacturer's pricing policies. We believe drug manufacturers, as pharmacists have done, must play a meaningful role in Medicaid cost containment efforts. The Medicaid program should have equal access to the best prices being offered by manufacturers to other purchasers. We are especially gratified that H.R. 5589 and proposals recommended by Senator David Pryor in the Senate recognize the important role played by pharmacists in health care.

I will focus my remarks on two professional issues which H.R. 5589 addresses: state drug utilization review and therapeutic interchange.

H.R. 5589 requires states participating in Medicaid to provide for a drug use review program to assure that prescriptions are "appropriate, . . . medically necessary, and . . . not likely to result in adverse medical results." The specifics of these provisions acknowledge the critical contribution of pharmacists to quality patient care through the provision of drug use evaluation and other cognitive services. Throughout the Medicare Catastrophic and more recent discussions of improved drug use that have occurred here in Washington over the past 3 years, APhA has worked diligently to increase Congress' understanding of the professional role of the pharmacist. As drug therapy has become increasingly complex, risky, and costly, the role of the pharmacist as a clinical care provider has become central to effective drug use.

This role has often been referred to on Capitol Hill in a sort of "shorthand"—prospective DUR. Yet, it is critical, Mr. Chairman, that this complex aspect of patient care not be viewed as merely the collection and communication of data across a point of sale device. Nor is it simply a list of rote counseling "points" or "reference standards."

The delivery of pharmacy care to the patient is a series of steps involving drug information analysis, patient data collection, physician and patient communication and ongoing monitoring and assessment. While systems which assist in this activity evolve and improve over time, it is the activities of the pharmacist—not the system—that will ultimately result in improving the drug therapy outcome for patients.

The literature is replete with studies which document improvements in the quality of drug therapy which result from the active involvement of pharmacists in the drug use process. That is why it is so critical that efforts to improve the use of drugs in the Medicaid program recognize and support pharmacists' provision of these clinical services.

H.R. 5589 also calls for a study by the Department of Health and Human Services of therapeutic interchangeability among pharmaceutical products including its scientific basis, usage by health care providers and potential adaptation to federally funded programs for the purpose of managing drug therapy and containing costs.

There has been much confusion on this issue. I am not aware of any group calling for pharmacists, on their own initiative, to substitute one drug product for another in filling a prescription order. We advocate therapeutic interchange—the use of a formulary system or drug list to guide drug therapy, and it happens every day in organized health care settings throughout our nation.

Therapeutic interchange was developed by physicians and pharmacists working together. The essential component is a drug list or formulary, which these health professionals developed using the best scientific and clinical information available to them. Such formularies or drug lists are developed locally by joint committees of physicians and pharmacists, and they are tailored to conform with unique practice patterns and to meet patient needs as they exist in that particular system.

Subsequently, as therapeutic interchange became more widespread, there arose among manufacturers intense competition to get their drugs into the formularies, and that competition most often resulted in severe discounting of drug prices to individual hospitals, nursing homes and health maintenance organizations. But although a major result of therapeutic interchange has been cost savings, one should never lose sight of the fact that its primary objective is not to obtain the lowest prices possible—it is to provide high quality patient care at the most cost-effective level possible.

Therapeutic interchange is a widely accepted component of drug therapy in the leading hospitals, nursing homes and HMOs throughout the nation. Most of you in this room who have received pharmaceutical care in the last 10 years from a hospital or nursing home in the United States have most likely had their therapy developed through the formulary and therapeutic interchange process. And now this concept has moved into the ambulatory care settings through health maintenance organizations and similar entities. For example, Kaiser Permanents—in which many Congressional staff members are enrolled—uses a formulary/therapeutic interchange process. Distinguished members of this Committee who have received their care at the National Naval Medical Center in Bethesda also have received the benefits of therapeutic interchange.

Therapeutic interchange is not second class health care as its critics claim. If it were, APhA could not support its use in the care that you, the leaders of our nation, receive or in the care received by Medicaid recipients who depend upon your leadership to meet their needs. We in the American Pharmaceutical Association fully support the practice of therapeutic interchange in ambulatory settings, so long as it meets standards comparable to those in organized health care settings. We also feel strongly that this system can be adopted to the Medicaid program and will prove to be a significant improvement over the current system, so long as physicians and pharmacists—the health practitioners best trained and who are directly involved with their patients—control the process. This program would bring together the knowledge of both physicians and pharmacists and enable them to use their unique expertise—shared expertise in pharmacology, physicians' unique clinical experience, physicians' knowledge of their patients and their diagnoses, pharmacists' unique knowledge of patients' drug-taking habits, pharmacists' complete records of drugs taken, and pharmacists' daily knowledge of the comparative costs of drug products.

In conclusion, Mr. Chairman, we appreciate the opportunity to appear before the Subcommittee. Legislation to reform Medicaid's drug pricing policies is needed and we look forward to working with the committee to achieve that objective.

Mr. Waxman. Thank you.

Mr. Bristow.

STATEMENT OF LONNIE R. BRISTOW

Mr. Bristow. Thank you, Mr. Chairman, and members of the subcommittee.

My name is Lonnie Bristow, a physician from San Pueblo, CA, also a member of the AMA board of trustees.

The American Medical Association appreciates this opportunity to address the proposals under Medicaid.

Medicaid prescription drug reimbursement has been identified as a primary target for cost cutting and reform. Some of the recent proposals have the potential to be truly dangerous to Medicare beneficiaries and we strongly oppose them.

Specifically, any Medicaid proposal which relies on the concept of therapeutic substitution should be rejected. The risk of therapeutic substitution stems from the fact that different patients may react to a drug differently for reasons of other medical conditions, interactions with other medications and factors such as the patient's age, race and individual sensitivity.

AMA has addressed strong opposition to a recent article which would rely on a therapeutic substitution scheme as part of deficit reduction efforts. Another part is S. 2605. Senator Pryor indicated his primary concern is that drug costs are detracting with the bill of Medicaid to provide adequate reimbursement and coverage for other needed benefits.

AMA shares some of Senator Pryor's concern but we have identified within S. 2605 several problems which would effect the quality of medical care for the beneficiaries.

AMA does not support the bill as introduced. But Senator Pryor deserves our commendation and sincere appreciation for the extensive work he has done on this issue.

In the last several days, Congressman Wyden, Congressman Cooper, and Senator Pryor introduced legislation which appears to offer a drug pricing approach similar to that offered by the drug companies themselves. This does not incorporate therapeutic substitution. It appears to address several items AMA has raised to the other legislation.

We are in the process of a thorough review and we will be communicating our position on it to the sponsors and the subcommittee in the near future.

AMA would not support any approach that would result in a diminished or second class level of care for the population served by Medicaid. We are confident that appropriate standard reform and savings of the Medicaid program should be realized.

We would like to address another issue that has been raised in Washington. That concerns prescription drug differential.

Triplicate prescription programs are an approach to gather information for use against prescription drug differential. I would urge the members of the subcommittee to refer to the materials AMA submitted for the detailed reasons we oppose triplicate prescription programs. We find them to be expensive, ineffective solutions which adversely impact patients with a legitimate medical need for controlled substances. Better alternatives for addressing prescription drug differential exists.

We call your attention to the AMA PADS program in our statement. The problem of controlled substance differential demands an efficient and effective response. This problem should not be an excuse for the economically motivated goal of deliberately reducing the appropriate medical use of cold substances.

While the drug abuser takes drugs to escape reality, nine cancer patients and those with arthritis or seizure disorders need to take the controlled substances to restore their ability to be contributing persons in society. We should not make a program that causes life to be any more difficult for these patients.

[Testimony resumes on p. 733.]

[The prepared statement of Mr. Bristow follows:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Health and the Environment
Committee on Energy and Commerce
United States House of Representatives

Presented by Lonnie R. Bristow, M.D.

RE: Medicaid Drug Reimbursement Proposals
and Prescription Drug Diversion

September 14, 1990

Mr. Chairman and Members of the Subcommittee:

My name is Lonnie R. Bristow, M.D. I am a physician in the practice of internal medicine in San Pablo, California and a member of the AMA Board of Trustees. With me is Michael Zarski of the AMA Division of Legislative Activities.

The American Medical Association appreciates this opportunity to address proposals for payment of drugs under Medicaid.

Before discussing these proposals, let me tell you about the Association's interest in improving Medicaid coverage for those in need. The AMA has devoted much attention to this issue. We have studied and identified the severe inequities in the current Medicaid program and we have concluded that the program is in need of reform. The AMA proposals to modify Medicaid include:

1. The creation of basic national standards of uniform eligibility for all persons below poverty level income (adjusted by state per capita income factors);
2. The creation of basic national standards of uniform minimum adequate benefits;

3. The elimination of the existing categorical requirements; and
4. The creation of adequate payment levels to assure broad access to care.

We recognize that the costs of these reforms will be great. Indeed, merely to continue providing the current level of care to Medicaid beneficiaries without such improvement will require increased resources.

Under these circumstances, we must be comprehensive in our examination of the elements that contribute to the cost of health care for Medicaid beneficiaries. One element that the AMA and others have studied recently has been prescription drugs. Prescription drugs are often the therapy of choice and can be the most cost effective treatment. The affordability of prescription drugs directly affects the nature and quality of care available to patients. Dramatic increases in the costs of prescription drugs can have a deleterious effect on access to care and patient compliance with prescribed treatment.

Physicians' concern over the cost of prescription drugs has led our Association to call on the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The AMA also prepared a report on the increases in prescription drug prices during recent years. A copy of that report is included with this statement. In our report, we state that the AMA supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied:

1. Physicians must have significant input into the development and maintenance of such programs;
2. Such programs must encourage optimum prescribing practices and quality of care;

3. All patients must have access to all prescription drugs necessary to treat their illnesses;
4. Physicians must have the freedom to prescribe the most appropriate drugs for the individual patient; and
5. Such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs.

Ever since Medicaid prescription drug reimbursement has been identified as a primary target for cost-cutting and reform, there have been a number of proposals introduced to accomplish this. Some of these proposals have the potential to be truly dangerous to Medicaid beneficiaries and we strongly oppose them. Specifically, any Medicaid proposal which relies on the concept of therapeutic substitution should be rejected.

The practice of substituting a drug different in chemical structure from the drug prescribed by the treating physician has been applied in some institutions as a cost-containment measure. The risk of therapeutic substitution to the patient stems from the fact that different individual patients may react to a drug differently for reasons relating to their other medical conditions, to interactions with their other medications, and to factors such as the patient's age, race, and individual sensitivity. The risk is compounded if the substitution occurs in an outpatient situation where the physician has no idea that a drug has been substituted for the one prescribed. It is essential that the treating physician have accurate knowledge of the patient's drug therapy in order to monitor for possible therapeutic failure or side effects. Moreover, where drugs are substituted on the basis of whichever is cheapest, patients especially those with chronic disease may be switched repeatedly to a different drug after being successfully stabilized on the original drug.

The AMA expressed strong opposition to a recent Office of Management and Budget (OMB) proposal which would rely on a therapeutic substitution scheme as part of deficit reduction efforts. We understand that the Department of Health and Human Services (HHS), among many others, has also expressed opposition to the OMB proposal and modification of the proposal is likely.

Another approach to this issue is Senator David Pryor's "Pharmaceutical Access and Prudent Purchasing Act of 1990" (PAPPA), S. 2605. Senator Pryor has indicated that his primary concern is the increasing cost of drugs under the Medicaid program and the fact that drug costs are detracting from the ability of Medicaid to provide adequate reimbursement and coverage for other needed benefits. Of special concern to Senator Pryor is that Medicaid often pays higher prices for drugs than other high volume drug purchasers. The AMA shares Senator Pryor's concerns regarding the impact of prescription drug prices on Medicaid programs in the states.

The AMA has identified in S. 2605 several conceptual and practical problems, especially with the concept of drug interchangeability and the administrative processes that would burden the physician's practice with further administrative requirements. The AMA, therefore, does not support the bill as introduced.

Senator Pryor and the AMA have continued to discuss the legislation and are addressing the profession's concerns with the bill, although spontaneous actions by pharmaceutical companies may render the bill unnecessary.

Companies within the pharmaceutical industry also have responded with cost-containment proposals of their own. These proposals, in general, take a straight-forward economic approach and do not incorporate those elements such as therapeutic substitution that cause us concern with the quality of patient care for Medicaid beneficiaries.

Overall, we are generally encouraged that the parties to this issue appear to show genuine concern for the quality of care of Medicaid beneficiaries. We are also encouraged by the flexibility demonstrated by the parties to this debate.

Certainly the AMA would not support an approach that would result in a diminished or second-class level of care for the population served by Medicaid. We are confident that appropriate substantive reform and savings to the Medicaid program can be realized this year.

PRESCRIPTION DRUG DIVERSION

We also would like to take this opportunity to address another prescription drug issue which has been raised here today. That issue concerns prescription drug diversion.

Triplicate prescription programs are an approach to gathering information for use against prescription drug diversion. They have the support of some state authorities and have been vigorously promoted by the federal Drug Enforcement Administration.

Program Features

Triplicate prescription programs are state-operated programs that require physicians to prescribe certain medications on special prescription forms provided by the state (for a fee). The prescriber is required to maintain a copy of the prescription on file for a period of years (except in the two states with duplicate prescription programs). The patient takes the remaining two copies to the pharmacy. The pharmacist in turn is required to keep one copy on file, and to forward the last copy to the state agency in charge of the program.

Triplicate prescription programs are intuitively appealing as a way of collecting "complete" information on the prescribing and dispensing of controlled substances. However, they have serious shortcomings.

Triplicate Programs Are Seriously Flawed

Triplicate prescription programs compare unfavorably with other approaches to drug data collection.

Triplicate prescription programs are expensive. Average costs of triplicate prescription programs have been reported to exceed $1 per prescription. Implementation costs initially must include funding for staff recruitment and training, software development and capital outlays for data processing hardware.

Triplicate prescription programs do not target aberrant behavior. Instead of attempting to identify and target problems, triplicate programs attempt to analyze all prescriptions for covered drugs. The volume of paperwork generated in these systems can easily result in backlogs of data. In Texas alone, more than 56,000 copies of prescription forms were received each month in 1986. In 1985, California estimated that at most 50% of the data received on prescription forms were actually entered into the system.

Triplicate prescription programs ignore and partially duplicate currently existing data bases. Triplicate programs make no attempt to integrate existing data bases. The result is that states spend scarce funds to collect redundant and unwieldy data instead of enhancing badly needed enforcement capability.

Triplicate prescription programs do not lead to effective interventions. Advocates of triplicate prescription programs point to decreases in overall use of controlled drugs as a measure of success.

However, decreases in use do not correlate with declines in abuse and diversion.

Comparison of metropolitan areas in states with and without multiple copy programs show a significantly higher frequency of emergency room mentions of Schedule II drugs in states with triplicate prescription programs.

There is a correlation between implementation of triplicate prescription forms and a decrease in the use of covered drugs. Texas is the only large state for which data are available for the periods prior to and following implementation of a triplicate prescription program. In the diagnostic categories of surgical aftercare, neoplasms, and fractures, after program implementation there was a shift away from Schedule II (covered) analgesics to Schedule III (not covered) analgesics. Such a shift was not seen in states without triplicate prescription programs. This shift, however, was not accompanied by a reduction in abuse of Schedule II agents.

The reasons for this reduced medical use of scheduled medications are many and complex.

Patients' privacy interests are a primary concern. Although incidents of unauthorized disclosure are alleged to be infrequent, fear of disclosure is real, and the latitude for authorized disclosure is broad.

The required procedures needlessly burden patients, financially and otherwise. Most programs limit prescriptions to a 30-day supply of medication. This means that patients must visit physicians more frequently than might be required clinically or must rely on the mail for new prescriptions. Physicians must factor this burden of effort, expense, inconvenience, and uncertainty into the decision making process when prescribing medication. Medications that are less than optimal therapeutically may be chosen for these reasons.

The requirement of the triplicate form places a stigma on the medication, the prescriber, and the patient, and suggests that something is suspect in the medical treatment. This implied negative message may lead the patient to resist treatment and threaten the integrity of the physician/patient relationship.

The requirement of the triplicate form intimidates prescribers (perhaps deliberately). The Public Health Service Interagency Committee on Pain and Analgesics has noted that fear of an unwanted "high profile" may lead physicians to prescribe only minimal (perhaps ineffective) doses of scheduled analgesic drugs.

An Alternative to Triplicate Prescriptions

The AMA has developed a different, more appropriate response to the problem of diversion of prescription drugs. This approach is the "Prescription Abuse Data Synthesis" or PADS program.

The PADS programs of the AMA are by far the most comprehensive approach to the gathering and analysis of diversion data. PADS integrates the national, state, and private-sector data sources. Its successor program, PADS II, augments state data processing capability with centralized data collection, analysis, and reporting. PADS III, currently under development, will be a wholly state-managed system. The PADS data analysis system is essentially an exception reporting system, which electronically sifts large amounts of information from numerous sources to detect suspicious patterns of activity.

The AMA maintains the PADS data bases, helps the states implement these programs, and provides technical advice and guidance to states on a nonprofit basis. Patient information is coded to assure confidentiality. Generally, all organizations within a state that are involved in control of prescription medications participate in the PADS program. In states where it has been implemented, the PADS program has been viewed as an economical and effective tool.

The PADS approach clearly fulfills the criteria for an effective prescription diversion data collection system.

PADS is cost effective. Data entry and programming are handled centrally, reducing costs for software and data entry personnel at the state level. Costs for the PADS II program average less than 10 cents per prescription. By comparison, data processing in triplicate prescription programs can cost more than $1 per prescription.

PADS efficiently and effectively targets aberrant behavior. PADS data are analyzed by exception criteria. Thus, PADS allows rapid identification of unusual activity based on volume of a drug or drug class prescribed, dispensed, or consumed, and on questionable drug combinations or routes of administration. The system is computerized rather than paper-based; its on-line capabilities give immediate access to state data. PADS has the ability to construct detailed profiles of practitioners, dispensers, or patients targeted for investigation through a single command.

PADS can generate information about a very broad variety of drugs. PADS data are not limited to Schedule II drugs. If a state believes there is a significant diversion problem with another type of drug, PADS can provide the information necessary for efficient investigation.

PADS does not affect use of medications for legitimate medical reasons. The PADS programs are not visible to physicians and patients, and thus do not interfere with physician prescription practices or make negative implications about medications, illnesses, or patients.

PADS builds on current data bases. The PADS programs integrate and synthesize the information available through a variety of existing sources. They provide information on practitioners, controlled substances in Schedules II through V, and designated noncontrolled drugs such as steroids, as well as transactions and patient activities. Data analysis and processing are conducted by the University of Chicago Computing Center.

PADS leads to interventions that decrease drug diversion. The AMA measures success by decreased morbidity and mortality related to abuse of prescription drugs. By this standard, the PADS programs are a resounding success.

By other measures, PADS is also successful. States average a savings of 10% of all Medicaid drug claims costs. Don Newman, a former Undersecretary of HHS, has called PADS "one of all too few stories of real success in the nation's War on Drugs." Numerous states and the GAO agree. The American Society of Addiction Medicine has endorsed the PADS system and recommended its adoption in all states based on its record of success.

In conclusion, the problem of controlled substance diversion demands an efficient, effective response. This problem should not be an excuse for the economically motivated goal of reducing the appropriate medical use of controlled substances. While the drug abuser takes drugs to escape reality, the cancer patient, those with arthritis or seizure disorders need to take drugs to restore their ability to function as productive and dignified members of society. We have submitted additional material on the AMA's PADS programs, triplicate prescription programs, and data on the prescription drug diversion problem.

And as stated earlier we are very encouraged that the issue of the cost of prescription drugs to the Medicaid program can be resolved to the satisfaction of all parties and with significant savings to Medicaid.

We will be happy to answer any questions you may have.

REPORT OF THE BOARD OF TRUSTEES

Report: O
(A-90)

Subject: Cost of Prescription Drugs

Presented by: John J. Ring, MD, Chairman

Referred to: Reference Committee E
(Charles D. Sherman, Jr., MD, Chairman)

The affordability of prescription pharmaceuticals directly affects the nature and quality of care available to patients. Recent, and in some cases dramatic, increases in the cost of prescription pharmaceuticals have had a deleterious effect on access to care and patient compliance with prescribed treatment. During the 1989 Interim Meeting of the House of Delegates, Resolution 112 was adopted. Resolution 112 asks that the AMA urge the pharmaceutical industry to exercise reasonable restraint in the pricing of drugs. The resolution also calls upon the AMA to study the justification for the sharp increases in prescription drug prices during recent years.

CONTRIBUTION OF PRESCRIPTION DRUGS TO HEALTH CARE IN THE UNITED STATES

The contribution of prescription drugs to improving the health of Americans and to containing the cost of health care is well recognized. Over the past century, new effective pharmaceuticals have helped in the virtual elimination of deaths in the United States from diseases such as poliomyelitis, pertussis, and tuberculosis and have contributed to a better than 30-year increase in average life expectancy at birth. Prescription drugs have been repeatedly cited by health economists as one of the most cost efficient of medical technologies.[1],[2] Often self-administered and generally requiring no expensive medical facilities, drugs have increasingly replaced other more expensive forms of therapy, forestalling hospital admissions, shortening hospital stays and reducing the need for costly invasive medical procedures. Currently, prescription drug costs account for less than 7% of each dollar spent on health care in the U.S.[3]

Past House Actions: I-89:301; A-88:273; I-85:229

THE COST OF PRESCRIPTION DRUGS IN THE UNITED STATES

The 1980s have witnessed a dramatic increase in the cost of prescription drugs. Between 1981 and 1988, the price of drugs in the U.S. rose 88%, a rate more than triple the general inflation rate of 28% for the period.[4] Although expenditures for prescription drugs represent only a small fraction of overall health care expenditures, the majority of drug purchases in this country are not covered by health insurance and must be paid for out-of-pocket by consumers.[5] For the poor, for persons dependent on high-priced pharmaceuticals for extended periods of time, and for the elderly living on fixed incomes who are major consumers of drugs, the cost of prescription drugs represents a major personal health-care expense.[6]

Since 1980, prescription drug prices have increased faster than general medical care prices and the prices of other goods and services (See Table 1).

Table 1: Consumer Price Index for Selected Goods and Services, 1980 - 1989

Year	All Goods and Services		Medical Care		Prescription Drugs	
	CPI-Urban	Percent Change	CPI-Urban	Percent Change	CPI-Urban	Percent Change
1980	86.3	13.6	77.6	11.0	75.2	9.2
1981	94.0	8.9	87.3	12.5	84.7	12.6
1982	97.6	3.8	96.9	11.0	94.9	12.0
1983	101.3	3.8	103.1	6.4	104.1	9.7
1984	105.3	3.9	109.4	6.1	114.4	9.9
1985	109.3	3.8	116.8	6.8	123.8	8.2
1986	110.5	1.1	125.8	7.7	134.9	9.0
1987	115.4	4.4	133.1	5.8	145.7	8.0
1988	120.5	4.4	142.3	6.9	157.1	7.8
1989	126.1	4.6	154.4	8.5	172.0	9.5

Source: U.S. Department of Labor, Bureau of Labor Statistics.

Approximately 50% of the increase in cost of drugs is attributed to the general increase in the consumer price index and about 3% of the increase is due to increases in the volume of drug purchases.

The remaining increase in the cost of drugs reflects increases in drug prices above the general rate of inflation and independent of prescribing practices.[7] Factors cited by the pharmaceutical industry as contributing to the rise in prescription drug prices include:

- the cost of research and testing including the cost of experimenting with drugs which did not prove to have therapeutic benefit;
- the cost of compiling clinical data and seeking and obtaining FDA approval;
- the cost of manufacture and production and of maintaining quality control;
- the cost of new drug promotion and physician education;
- the limits of patent protection and competition from generics;
- uncertain market life and competition from fast follower drugs;
- competition from overseas producers;
- product liability; and
- the need to provide adequate shareholder returns.[8-12]

DRUG RESEARCH AND DEVELOPMENT

A major factor driving the cost and, ultimately the price of pharmaceuticals is the high cost of drug research and development (R&D). A 1986 study conducted for the Pharmaceutical Manufacturers Association (PMA) estimated that it took, on average, 10 years and $125 million to get one medication from the laboratory to the pharmacist's shelf.[13] Preliminary data from a more recent study by Tufts University Center for the Study of Drug Development adds two years and more than $75 million dollars to the PMA's estimate of the lead-time and cost of developing a marketable drug.[14]

The profitability of individual drug firms depends largely on the continual introduction of successful new products. Thus, research and development is key to industry growth and survival. During 1989, U.S. drug companies reinvested nearly 17% of their pharmaceutical sales revenue ($7.3 billion) into drug research and development. This represented a 12.3% increase over the industry's 1988 R&D investment of $6.5 billion.[15] Pharmaceutical R&D funding has accelerated over the past decade, doubling every five years.[3,16] Yet despite one of the highest levels of R&D funding of any manufacturing industry in the United States, only a small proportion of this investment eventually results in saleable products.

Drug research and development is both expensive and risky.[17-20] R&D costs for new drugs can vary widely and there is no apparent relationship between the magnitude of these costs and success in the marketplace.[21] The Upjohn Company estimates that of every 2,000 chemicals studied by its laboratories, only 200 show any potential in early tests, and of these, only 20 may eventually be tested in people. Only one experimental drug out of the original 2,000 chemicals studied by Upjohn scientists may be found safe and effective enough to pass Food and Drug Administration (FDA) review and reach the market.[22] The PMA estimates the R&D success rate for new pharmaceuticals at an even gloomier one in 10,000.[9]

A major study of the cost of new drug development is being conducted by Tufts University Center for the Study of Drug Development under the direction of Joseph A. DiMasi, PhD, in collaboration with Henry Grabowski, PhD, of Duke University and Ronald Hansen, PhD, of the University of Rochester. The study, which is based on a 1987 national survey of pharmaceutical firms, examines in detail the actual expenditures by year and stage of development invested by participating companies in the development of new chemical entities. Results of this study are expected to be available by June or July of 1990.[23] The results will be communicated to the House of Delegates in a follow-up report on pharmaceutical drug pricing.

DRUG DEVELOPMENT AND THE FDA APPROVAL PROCESS

Compliance with FDA requirements for new drug approval adds to the cost of drug R&D in the U.S. Designed to help assure that only safe and effective medicines come to market, the FDA drug approval process formally begins with the filing of an investigational new drug (IND) application and culminates with the review and approval of a new drug application (NDA). For new drugs approved in 1989, the FDA required an average review time of 32.5 months just to review and take action on the NDA. However, years of basic research and laboratory and animal studies precede the submission of an IND and additional years of clinical trials in humans precede submission of the NDA. Even after the approval of the NDA, the FDA requires drug companies to continue to submit periodic reports that document adverse reactions to the drug, quality control records, and, for some drugs, long-term effects.[24]

According to W. Leigh Thompson, MD, group vice president of Lilly Research Laboratories, one of the major factors contributing to the rise in drug research costs is the increasing amount of information required to support new drug applications (NDAs) for the FDA--in particular "the expansion of the magnitude of clinical trials." Doctor Thompson illustrates this increase by pointing to the differences in clinical trial requirements for the 1979 approved antibiotic, Ceclor® (Cefaclor) and a similar related antimicrobial now under development at Lilly. While the clinical trials for

Ceclor® involved 1,493 patients, the clinical trials for Lilly's new antimicrobial will involve 10,000 patients. According to Thompson, the number of routine clinical laboratory tests have doubled every two years and the number of pages of clinical report forms submitted in NDAs have doubled every year and a half. The NDA for Lilly's recently developed Pindac (pinacidil), a vasodilator currently under review at the FDA is 470,000 pages in length.[25] "Technology inflation" has also played a part in the added cost of drug R&D as laboratories try to streamline basic research through the use of computer generated three dimensional molecular models.[26]

THE OUTCOME OF DRUG R&D

In 1989, 23 new drugs, i.e., new molecular entities (NMEs), obtained FDA approval and according to a recent PMA survey, there are currently 67 new drug applications (NDAs) awaiting FDA review in 1990.[27] The length and total cost of the research and development effort that resulted in the 23 FDA approved drugs in 1989 and that supported the 67 NDAs for 1990 are difficult to estimate. Drug manufacturers have argued that increases in pharmaceutical prices are necessary to cover the large and growing expense of research and development for new drugs.[28] Industry critics have countered that many of the new drugs coming out of this R&D effort offer little or no therapeutic advantage over existing products.[29]

In a majority staff report on the July 1989 Congressional Drug Pricing Hearings, the Senate Special Committee on Aging questioned the pharmaceutical industry's justification for high new drug prices based on high R&D costs and the value of drugs as new effective therapies. Using the FDA's evaluations of new drug therapeutic potential ("A" rated--important therapeutic gain; "B" rated--modest therapeutic gain; "C" rated--little or no therapeutic gain), the staff report concluded that class "C" drugs, those whose treatment potential was judged by the FDA to be essentially the same as existing drugs already in use, comprised 84% of the 348 new drugs marketed by the 25 largest drug companies between 1981 and 1988. Only 4% of this group of new drugs received an "A" rating from the FDA meaning they offered an important therapeutic gain over existing products. The report argued that Class "C" drugs, described as "me too" drugs, offer little economic advantages to the patient over existing drug products and, therefore, should be priced lower.[29] However, many of these new drugs are priced significantly higher than the older drugs they seek to replace.[30]

The PMA criticized the committee's staff report in their own report, "America's Pharmaceutical Research Companies:

A Cost-Effective Source of Important New Medicines." According to the PMA, the Senate staff analysis inappropriately lumped new molecular entities (NMEs), which account for approximately 80% of all industry research expenditures, with improvements to existing products, which almost invariably would be rated class "C" by the FDA. The PMA states that of 182 NMEs approved by the FDA between 1981 and 1988, 47% were considered to represent significant or moderate therapeutic gains.[28]

The PMA has also taken issue with the use of the FDA's rating system as a measure of the ultimate or even current value of drugs on the market. Designed only to serve as an FDA administrative tool to allocate reviewing resources, the rating system does not take into account that a drug's actual value to patient care evolves with widespread use.

Studies of new drug development show that many of the major pharmaceutical advances of the past 50 years have involved "me too" and "follow on" research.[29] These studies stress that "molecular modification is the essence of effective pharmacology" and the foundation of many original drug advances. For example, four important therapeutic classes of drugs--sulfonamide antimicrobials, diuretics, uricosurics, and oral antidiabetic agents--were ultimately derived from the drug prontosil, developed by Domagk in the 1930s. Molecular changes in mercaptopurine, a chemotherapeutic agent, led to allopurinol, a xanthine oxidase inhibitor used to treat gout, and azathioprine, an immunosuppressant; cocaine, an analgesic, eventually gave rise to the cardiovascular and anesthetic drugs procainamide, lidocaine, bupivicaine, and tetracaine; and research on norepinephrine's chemical structure led to alpha-methyldopa, an antihypertensive. A 1988 Tufts University study of the World Health Organization's essential drug list found that nearly half of the drugs considered essential by the WHO were not innovator drugs in their respective therapeutic classes but were the result of "me-too" and "follow-on" drug research.[31]

DRUG PATENT PROTECTION AND MARKET LIFE

Once a drug is on the market, the manufacturer prices the drug to recoup R&D costs and support ongoing operations. The market life of a new drug is uncertain. Competing manufacturers are continually introducing new products which they claim are as good as or better than drugs already on the market. Thus, at any time a more efficacious drug may appear and curtail an existing drug's market life even before the end of its patent life. Before a drug reaches the market, its patent life of 17 years is eroded by the length of its R&D period. The average remaining patent life for drugs after FDA approval is about nine years.[32] Once the drug goes off patent, it can expect competition from lower priced generic drugs.

GENERIC DRUGS

Since the passage of the Drug Price Competition and Patent Term Restoration Act in 1984, the number of generic drugs developed has accelerated in the U.S. prescription drug market. The act facilitated quick FDA approval, via the Abbreviated New Drug Approval (ANDA) process, for generic drugs which were chemically equivalent and bioequivalent to FDA-approved brand name (innovator) drugs. (As a quid pro quo, the act also allowed manufacturers of innovator products to recoup some of the patent life lost on their drugs because of the length of the FDA's approval process.) Today, generic drugs comprise about 30% of U.S. retail drug sales.[33] Many of these generic drug products are manufactured by brand name drug companies. The share of the prescription drug market held by generic products is expected to expand as more brand name (innovator) drug products come off-patent (See Table 2)[34] and generic prescribing and generic substitution become more widespread.

Table 2: Major Drugs Losing Patent Protection 1991-1995.

Year of Patent Loss	Drug	Therapeutic Target	Manufacturer	Estimated Sales (in millions)
1991	Procardia	Heart	Pfizer	$228
	Tenormin	Heart	ICI	250
1992	Cardizem	Heart	Marion	300
	Ceclor	Antibiotic	Eli Lilly	191
	Feldene	Arthritis	Pfizer	208
	Seldane	Antihistamine	Dow	118
1993	Corgard/Corzide	Heart	Squibb	115
	Lopressor	Heart	Ciba-Geigy	169
	Naproyn	Arthritis	Syntex	275
	Xanax	Tranquilizer	Upjohn	235
1994	Tagamet	Ulcer	SmithKline	523
1995	Capoten	Heart	Squibb	207
	Zantac	Ulcer	Glaxo	500

Source: Generic Pharmaceutical Association as cited in Wall Street Journal, February 20, 1990.

Generic drugs often are much less expensive than the brand name (innovator) products they mimic. This price break is largely due to the fact that generic drug manufacturers do not incur the high risk and high costs of pioneering drug research and development. The major task of generic manufacturers is to demonstrate bioequivalence to the innovator drug product and secure FDA approval for their ANDA. Because the market for a generic product is already established by the brand name drugs they copy, the promotional and advertising budgets of generic drug producers are relatively small.

To compete with generics, brand name companies have chosen to raise rather then lower the price of their off-patent products.[35] The rationale is that there will be a post-patent period of continued brand loyalty among prescribers and patients. Although the number of sales of the brand name drug will fall as generics make inroads into the market, higher prices for the former may, for a time, offset market share losses to generic competitors.

Other strategies to retain market share in the face of generic competition include changing the appearance of the drug to increase patient recognition and brand loyalty, aggressive advertising compaigns which warn physicians of potential therapeutic inequivalencies of generic products, and modification in the drug delivery system which can potentially extend the patent life of the brand name drug. Pioneering drug firms also may establish or upgrade their own generic drug divisions to remain competitive in the therapy areas addressed by their brand name products. This strategy realistically accepts that brand name drugs, like other products, have a market life cycle and that the generic market will most likely become a permanent and growing part of the drug market. Generic substitution is permitted in all 50 states and a growing number of reimbursement programs either require or strongly encourage the use of generic drugs.[36] In 1990, only 21 of the current top 100 U.S. prescription drugs will have some form of patent protection.[32]

While competition from generic drugs has had the effect of boosting the price, at least in the short term, of specific brand name pharmaceuticals, increased use of lower cost generics in the place of brand name drugs should lower overall drug expenditures. Barriers to the growth of generic prescribing and substitution include physician resistance or indifference and physician and public concern over the quality of generic drugs.

DRUG PROMOTION AND MARKETING

Brand name prescription drugs are marketed directly to physicians. From a marketing viewpoint, it is important for a drug company to be the first on the market with a major drug innovation and to quickly develop brand name recognition for that drug within the medical community. Studies of physician prescribing practices consistently show that physicians are brand loyal.[7,37]

Advertising and promotional campaigns directed toward physicians are highly technical and often considerably more expensive than those directed toward the general public. The proportion of sales revenue devoted to product promotion is higher for drug manufacturers than for manufacturers of many other products. Because the pharmaceutical industry is continually introducing new products and responding to the claims of new competitors, advertising and promotional strategies must be continually changed and updated adding to the overall cost of drug promotion. As the prescription drug market has become more competitive, the promotional budgets of major drug firms have increased. In 1980, the U.S. pharmaceutical industry spent $754 million for promotion. The following year this figure increased 19% to $898 million.[38]

A large proportion of promotion budgets of drug companies are used to support the activities of field representatives or "detail men" who call upon physicians, pharmacists, and hospital purchasing agents. This one-on-one process is a very expensive way of advertising a product. Most drug companies believe that the size of detail forces directly influences market share. On average, 70% of drug company promotional expenditures are allocated to support sales forces. Between 1983 and 1989, the number of sales people at the top 30 most profitable U.S. drug companies increased 50%. By 1993, this detail sales force is expected to grow another 25%.[39]

INTERNATIONAL COMPETITION

Another factor affecting the pricing of drugs is international competition. Sixty-six percent of the total ethical pharmaceutical sales of U.S. drug firms in 1989 were domestic and 34% were foreign. The major foreign consumer of U.S. pharmaceuticals is Western Europe, followed by the combined market of Japan, Australia, and New Zealand. Anti-infectives comprise the largest class of drugs exported by the U.S.; cardiovascular drugs and central nervous system products rank second and third.[15]

There is a marked price differential between the cost of drugs in the U.S. and elsewhere in the world. The pharmaceutical industry has argued that much of the price differences by country reflect currency fluctuations. Other factors contributing to drug price differences between countries include variations in approval times between discovery and market entry, in standards of medical practice, in customary dosages, in packaging and wholesale and retail mark-ups, and in price control and drug reimbursement systems.[40]

Because the cost of R&D is lower overseas than it is in the U.S., a number of U.S. drug firms have begun to export this work. The length of the drug approval period also is much shorter overseas than in the U.S. Thus, a growing number of drugs submitted for FDA approval are already in approved use in Europe and elsewhere. Eighteen of the 23 new molecular entities (NMEs) approved by the FDA in 1989 were approved in another country first.[27] Differences between drug R&D in the U.S. and elsewhere in the world, differences in the financing of drug purchases, and currency fluctuations make a one-on-one comparison of drug prices between countries difficult.

PRODUCT LIABILITY

Another major difference that distinguishes the United States pharmaceutical market from many foreign markets is our product liability and tort system which adds to the cost of drugs in this country. According to the PMA, the number of product liability lawsuits filed in federal district courts has been increasing rapidly. Between 1986 and 1988, the number of cases in the U.S. district courts increased 26% from 13,595 to 17,104. Compliance with FDA drug approval regulations does not provide drug companies with immunity from product liability action.[13] A portion of the rise in drug costs represents the potential financial risks posed by product liability suits. Product liability considerations also have affected R&D. This is particularly true in the case of vaccines.[41]

DRUG PRICING AND THE ECONOMICS OF THE PHARMACEUTICAL INDUSTRY

To date, the pharmaceutical industry has resisted releasing detailed information on the pricing of drugs, considering this information to be proprietary. It is clear from a business standpoint, that the revenue realized through the sale of pharmaceuticals must support private drug research and development, marketing costs, manufacturing and distribution costs, and other operational expenses.

Critics of the industry have alleged that new drug prices are often 49% above the price of therapeutically comparable drugs already on the market.[42] High prices allow drug companies to recoup R&D costs in the early phases of a drug's product life. Premium pricing also acts as a market signal that the product is new, different, and presumably in some way better than the lower cost drug(s) it seeks to replace. As discussed above, premium pricing also occurs at the end of a brand name drug's market lifecycle when it goes off patent. Higher prices for newly off patent drugs allow drug manufacturers to capitalize on brand loyalty in the face of generic competition.

The pharmaceutical industry has been very successful in the pricing of its products and is today one of the most profitable and competitive industries in the country. United States drug sales increased 10.2% in 1987, 12.5% in 1988, and 13.1% in 1989. Foreign sales of U.S. drug companies increased 15.6% in 1987, 8.2% in 1988, and 8.4% in 1989. The pharmaceutical industry is thus one of the few major U.S. manufacturing concerns that is currently experiencing a positive balance of trade.[15]

In 1989, the pharmaceutical industry realized a 15.1% after-tax profit on sales, a return which was nearly three times the combined after-tax profit on sales experienced by all manufacturing enterprises in the United States that year. The after-tax return on stockholders' equity (RSE) has also been strong for the pharmaceutical industry. For the first three quarters of 1989, the after tax RSE was 28.6% for the pharmaceutical industry, nearly double the after tax RSE for all U.S. manufacturing (see Table 3).[43]

Table 3 : Pharmaceutical Industry and Manufacturing Industry Profitability, 1980-1989.

Year	Pharmaceutical Industry		All Manufacturing Industry	
	After Tax Return on Sales	After Tax Return on Stockholders' Equity	After Tax Return On Sales	After Tax Return on Stockholders' Equity
1980	13.2%	19.9%	4.8%	14.0%
1981	10.9	16.9	4.8	13.7
1982	13.1	19.7	3.5	9.3
1983	13.4	20.3	4.0	10.6
1984	13.3	20.2	4.6	12.4
1985	10.9	16.5	3.8	10.1
1986	14.5	22.9	3.7	9.6
1987	10.5	17.4	4.9	12.7
1988	16.0	30.4	5.9	16.0
1989	15.1	28.6	5.3	14.4

Source: *Quarterly Financial Review* as cited by G.S. Persinger, Assistant Vice President of Industry Studies, PMA, in January 26, 1990 letter to AMA Department of Drugs.

Despite the pharmaceutical industry's strong market performance, there are signs that it may be heading for more turbulent times. Since the 1970s the industry has been affected by a trend toward consolidation and takeover as drug firms worldwide seek to buy their way into new markets and acquire promising R&D ventures. The largest drug company worldwide is Merck with $5.9 billion in annual sales. However, Merck controls just 4% of the world market for pharmaceuticals.[26] The U.S. drug market is similar to the global market in that no single company dominates. However, as competition increases both within the U.S. and internationally, only the largest drug firms will have the resources necessary to support aggressive, long term R&D programs and expensive marketing campaigns (See Table 4).

Another signal of market change for the pharmaceutical industry is the fact that a number of drug products will lose their U.S. patents over the next five years. These include flagship drugs such as Pfizer's Procardia; Marion Laboratories' Cardizem; Eli Lilly's Ceclor; and SmithKline Beckman's Tagamet. According to Salomon Brothers analyst, Robert Uhl, by 1995, over $2 billion in domestic brand name drug sales for U.S. companies will be exposed to generic competition. Uhl and others have observed that there appear to be few new "blockbuster" drugs in the pipeline to replace these "star" products.[26]

The rate of drug innovation also appears to be slowing. The major health threats currently facing the U.S.--heart disease, cancer, neurological disorders, diseases of aging and viral diseases like AIDS have proved to be elusive therapeutic targets for drug R&D efforts. While some drug companies have continued to realize large returns on their R&D investments, others have been less fortunate.

DEMAND SIDE FACTORS AFFECTING DRUG PRICING

So far this report has reviewed many of the supply side factors that contribute to the rising cost and price of prescription drugs. These include research and development costs, competitive pressures, and the need to comply with FDA regulations. Demand side factors also affect the market for drugs and the way these products are priced. Demand side factors include physician prescribing and patient buying practices.

Prescription drug purchases are initiated by physicians who prescribe for patients. Physicians define the amount, frequency, and duration of a drug's use and whether a brand name or generic drug will be used. In states which allow generic substitution by pharmacists, it is still the physician who has the authority to

Table 4: Major Pharmaceutical Companies

Company	Country	Sales		Earnings (millions)	Return on Assets	R&D Expenditures (millions)	World Rx Market Share	
		Rx (millions)	Total (billions)				1983	1988
Merck	USA	$4,240	$5.94	$1,207	19.7%	$615	3.95%	3.80%
Glaxo Holdings	UK	3,160	3.52	976	22.4	404	3.0	1.4
Ciba-Geigy	SWZ	3,020	12.73	865	6.5	440	2.8	3.2
Hoechst	GER	2,700	23.53	973	5.3	330	2.5	3.0
American Home Products	USA	2,420	5.5	932	20.2	250	2.25	3.1
Bayer	GER	2,370	23.65	954	4.7	480	2.2	2.0
Johnson & Johnson	USA	2,350	9.0	974	14.9	385	2.2	2.3
SmithKline Beckman	USA	2,300	4.75	476	10.7	285	2.15	2.8
Pfizer	USA	2,260	5.39	791	11.4	380	2.1	2.9
Sandoz	SWZ	2,230	7.26	493	6.6	390	2.1	2.0
Eli Lilly	USA	2,090	4.07	761	14.5	375	1.95	2.5
Bristol-Myers	USA	2,010	5.97	829	16.0	275	1.9	2.1
Hoffmann-La Roche	SWZ	1,940	5.79	427	4.2	470	1.85	2.2
Squibb	USA	1,710	2.59	426	13.8	275	1.6	1.3
Schering-Plough	USA	1,670	2.97	390	12.3	300	1.55	1.7
Upjohn	USA	1,650	2.75	353	11.3	320	1.55	1.6
Warner-Lambert	USA	1,590	3.91	340	12.6	220	1.5	1.9
American Cyanamid	USA	1,560	4.59	306	6.7	190	1.45	NA
Takeda Chemical Inds	JAP	1,480	5.06	304	4.5	NA	1.4	1.1
Abbott Laboratories	USA	1,450	4.94	752	15.6	250	1.35	1.1
Imperial Chemical Inds	UK	1,450	21.06	1,586	18.1	240	1.35	1.6
Beecham Group	UK	1,400	4.68	458	10.5	140	1.35	1.4
Wellcome	UK	1,340	2.11	215	10.1	205	1.25	1.1
Rhone-Poulene	FRA	1,300	10.72	342	3.0	250	1.2	1.6
Sankyo	JAP	1,190	3.25	96	3.4	NA	1.1	1.4

Source: Financial World, May 30, 1989, p. 77.

insist on the use of a brand name drug. Although physician generic prescribing is on the increase, it still represents a relatively small proportion of all prescription orders. As noted above, barriers to generic prescribing include a lack of information or belief in the therapeutic equivalency of generic and brand name drugs, concern over the quality of generic products, and a lack of physician information regarding the availability of generic drugs.

In general, patients are even less informed than physicians about generic drug products. In addition, on the retail level, there is considerable variability in the price of prescription drugs, even within the same market area. According to a 1989 American Association of Retired Persons report on pharmacy surveys in the same community, the price of an identical prescription could be twice as much or more at one pharmacy as at another, and typically price differences of 25% can be found among half a dozen or fewer pharmacies in the same community. Furthermore, although, on average, generic drugs cost half as much as brand name drugs, generics at some pharmacies may cost more than their brand name counterparts at other pharmacies. The AARP survey also found substantial price differences for the same drug both within the same state and across states.[44]

Patients often do not comparison shop for prescription pharmaceuticals. If the price of a prescription drug is beyond their financial means, the patient may forego purchasing the drug or may take fewer pills than what is prescribed. The lack of insurance coverage for prescription medicine can be a significant barrier to quality care for many low and moderate income persons.

DRUG COST CONTAINMENT MEASURES

Most health insurance programs in the U.S. do not cover drug expenses and pharmaceuticals have not, historically, been the target of cost-containment measures.[7] Prescription drugs are covered by some HMO plans and state Medicaid programs. These programs, along with large institutional and group purchasers of pharmaceuticals, have been the innovators in drug cost containment.

Although prescription drug coverage is an optional benefit under Medicaid, 48 of 51 Medicaid jurisdictions provide this coverage. Faced with increased demands for services and limited budgets, state Medicaid programs have begun to institute policies aimed at containing the cost of drugs used by their enrollees. Medicaid program drug cost control strategies include:

- Restrictive formularies--lists of drugs that are approved for coverage;

- Copayment requirements--requirements that enrollees pay a part of drug charges;

- Maximum payment limits for all dispensed drugs--prescription drug payments capped at a fixed dispensing fee plus an amount to cover drug ingredient costs (usually the average wholesale price of the drug);

- Dispensing restrictions--limits on the amount of drugs that can be dispensed at any one time or on the number of covered prescriptions that can be reimbursed in any one month;

- Drug utilization review--formal review of the medical appropriateness and therapeutic implications of patient drug use.[7]

The effectiveness of these cost-containment programs has received mixed reviews.

Restrictive formularies are in use in about 20 Medicaid programs and are generally applicable only for outpatient drug use. Restrictive formularies limit program drug coverage to those drug products on an approved list. Limited or restrictive formularies allow Medicaid programs to channel most or nearly all drug purchases for a given therapy to a limited number of suppliers. This forces drug suppliers to compete on price. In exchange for price discounts, the supplier is assured a captured market for their drugs.[7]

Drugs are included in drug formulary lists based on the perceived needs of program enrollees, the therapeutic properties of the drugs, and their price. Drug formularies frequently consist of a set of lower-priced drugs which are felt to be therapeutically equivalent to higher-priced drugs. Drugs not on the formulary list are usually not eligible for Medicaid coverage although many state programs have prior authorization mechanisms which allow special exceptions to the closed list if a physician documents that an alternative drug is necessary for a particular patient.

Recent studies of Medicaid drug formularies have concluded that while these programs may reduce Medicaid drug costs, these cost savings are offset by the substitution of more costly services such as increased physician visits and hospitalization. The net result is that overall Medicaid costs may rise. A recent Louisiana State University study of restrictive Medicaid drug formularies, sponsored by the PMA, concluded that, on average, restrictive formularies may cause a 4 to 15% increase in a state's total Medicaid expenditures. The study found that patients who are prescribed less efficient, lower-cost drugs instead of restricted drugs may take larger amounts of the former or take these drugs for longer periods. Alternatively, these patients may be hospitalized. Inpatient hospital care costs for mental patients may rise 20 to 31% when this care is substituted for new drug treatments which are not included in the formulary. Restrictive formularies have also been found to exert strong upward pressure on the use of physician services raising Medicaid expenditures for this care by an estimated 28 to 37.6%.[45,46]

There is also growing concern that Medicaid formularies may compromise the quality of care provided to Medicaid recipients.[47] Medicaid patients may receive less than optimal care because of the inevitable time lag before new pharmaceuticals are reviewed and approved for inclusion in the formularies and because lower-cost, less-effective drugs which are included in these formularies may require a higher level of patient compliance to achieve the same therapeutic effect as off-formulary drugs. Not all studies of Medicaid formularies are so pessimistic about their potential to achieve program savings, but it appears that to be effective this cost-containment strategy must be part of a larger, more comprehensive program of utilization review and cost control.[46]

Another drug cost-containment strategy is the requirement of a patient copayment when a drug is purchased. Studies of these programs have consistently shown that they reduce drug program expenditures. However, the impact of these requirements on the utilization of other covered services and on overall Medicaid program expenditures has not been studied.[48] In an examination of drug cost containment strategies, Wagner and Duffy suggest that to the extent that copayment discourages consumers from filling prescriptions, it may negatively affect health outcomes.[7]

Medicaid drug costs have also been controlled through the use of maximum payment limits which cap the amount a Medicaid program will pay for any given drug. A special type of maximum payment program is the Maximum Allowable Cost (MAC) program. Federal regulations for the MAC program were issued in 1976. Over time these regulations have expanded to include price limits on a growing number of drug entities for which there are three or more suppliers. The MAC program sets ingredient price limits based on a review of the wholesale prices of all competing manufacturers of a given generic drug. State Medicaid MAC programs may include drugs in addition to those on the federal MAC list. Two major 1980 government sponsored studies of the MAC program concluded that it produced significant Medicaid cost savings. Although these studies have been criticized for not using a representative sample of states and drug products, for underestimating administrative costs, and for not examining the impact of MAC limits on other payors,[51] the MAC program has probably resulted in Medicaid savings particularly as more generic drugs have come into the market.

Dispensing restrictions either limit the quantity of drugs or the number of prescriptions that are covered by Medicaid for an enrollee in a given month.[7] Programs which limit the quantity of Medicaid covered drugs dispensed at any one time have been shown to save program expenditures. Programs which limit the number of Medicaid covered prescriptions in a given period have been shown to have the same impact as restrictive formularies--namely that while Medicaid drug expenditures may be lowered, there is an overall increase in total program expenditures because other health care services are substituted for prescription drugs. The health status of the elderly and the disabled, two patient populations characterized by the highest level of multiple prescription use, may also be seriously compromised by these programs.[7]

Drug utilization review programs have not been well studied.[7] Such programs, when appropriately designed, may improve the quality of patient care. Whether the administrative cost of these programs outweigh any drug cost savings is unclear.

Major private institutional or large group purchasers of pharmaceuticals including multihospital groups, HMOs, and pharmacy groups, have also instituted drug cost-containment measures. In addition to the aforementioned strategies, these private major drug purchasers have sought negotiated discounts from manufacturers and wholesalers in the price of drugs through group purchasing.

DRUG LEGISLATION

The pharmaceutical industry has vigorously resisted participating in drug cost-containment programs, particularly restrictive formularies, arguing that these programs reduce patient access to quality medicines and impede drug R&D. According to the PMA, drug "formularies undermine patient protection, and patent protection."[8,52] If companies agree to negotiate lower prices for drugs that are still on patent, the patent system itself will be undermined because the economic advantages of new drug discovery will be diluted.

Previous Congresses have supported legislation encouraging investment in drug research and development and drug patent protection. Examples of recent legislation supporting drug R&D and patent protection include the Orphan Drug Act of 1983 and the Drug Price Competition and Patent Term Restoration Act of 1984. In addition, the FDA has been encouraged to speed up the drug approval process. In 1987, the FDA revised its Investigational New Drug Application regulation and in 1989 the FDA permitted expedited review of new medicines for serious and life threatening diseases.[53]

A different attitude toward the pharmaceutical industry appears to be developing in the 101st Congress. The continuing rise in pharmaceutical prices and the impact these price increases are having on the cost of public health care programs and access to health care, has raised concern within Congress and the health care community about the cost and affordability of drugs in the U.S.[4] In July and November 1989, the Senate Special Committee on Aging held public hearings on the pharmaceutical pricing issue. At those hearings, Sen. David Pryor (D-AK), chairman of the committee, accused drug companies of charging "exorbitant prices" and turning out too few "breakthrough drugs" and too many "me too" drugs. Senator Pryor also announced his intention to introduce legislation to enable state Medicaid programs to institute measures which would allow them to achieve drug discounts and savings.[42] According to a Jan. 23, 1990, letter from the senator to the PMA, the proposed legislation will encourage Medicaid buying groups. Senator Pryor has also stated that the proposed legislation will not resort to restrictive formularies, but that lists of therapeutic alternatives will be necessary.[54]

Senator Pryor's bill is expected to generate lively debate about prescription drug pricing. Major points of discussion will include the role of government in drug cost containment, the dangers of therapeutic substitution in the out-patient setting, the effectiveness of drug formularies and other cost-containment programs in controlling health care costs, and the direction and value of current drug research and development efforts.

Representative Stark (D-CA) has also raised the issue of pharmaceutical price increases particularly in the area of vaccine prices. When Congress reconsiders drug R&D tax credits, which were extended through September 1990 in the Omnibus Budget Reconciliation Act of 1989, the issue of pharmaceutical pricing and the need for drug manufacturer R&D tax credits may be brought to the table.

CONCLUSIONS

Prescription drugs are among the most cost-efficient forms of medical technologies and, presently, they account for less than 7% of every dollar spent on health care in the U.S. However, over the past ten years, the prices of prescription drugs have increased faster than general medical services and have tripled the general rate of inflation for the period. Approximately 50% of the increase in prescription drug prices cannot be explained by the general increase in the consumer price index or by an increase in the volume of drug purchases and, thus, is directly related to price increases. The pharmaceutical industry cites a number of factors as contributing to the rise in prescription drug prices. These include rapidly rising R&D costs, lengthy FDA approval times, uncertain market life due to competition from fast-follower drugs, the limits of patent protection and competition from generic drugs, competition from overseas producers, increased product liability, and the need to provide adequate shareholder returns. However, during the 1980s, the pharmaceutical industry has consistently realized after-tax profits on sales that were two- to three-fold greater than the combined after-tax profits on sales experienced by all other manufacturing enterprises in the United States. Furthermore, the after-tax return on stockholders' equity for the pharmaceutical industry has consistently outpaced the after-tax RSE for all U.S. manufacturing.

Prescription drugs frequently are not covered by health insurance programs and the rapidly rising prices in prescription drugs can have a deleterious effect on access to care and on patient compliance with prescribed treatment. This is especially a problem for individuals with low to moderate incomes. For those insurance programs that do provide prescription drug coverage, including state Medicaid programs and some managed care (e.g., HMO) plans, drug cost-containment mechanisms frequently are introduced. However, the effectiveness of these programs in terms of maintaining high quality care and in their ability to reduce the overall cost of health care to the programs is questionable.

Growing concern about the cost of drugs and the effect on the quality and accessibility of care available to patients and increased legislative debate on strategies for containing public health care program expenditures for pharmaceuticals underscore the importance of the American Medical Association's involvement in this area.

The AMA will monitor the ongoing study by Tufts University of the cost of drug development and its relationship to drug pricing as well as other major research efforts in this area and keep the House of Delegates informed about the findings of these studies.

In addition, the AMA continues to work with the pharmaceutical industry to address patient access and quality of care issues which arise because of increases in pharmaceutical costs, lack of insurance coverage for pharmaceuticals, and R&D concerns. More work needs to be done to increase patient access to affordable effective drug therapies. The pharmaceutical industry must accept greater responsibility in the pricing of its products, looking not only to business concerns but also to the impact that increases in drug prices can have on the health care of patients.

The health care insurance industry should be encouraged to reconsider its limited coverage of needed pharmaceutical products which may substitute for more costly covered services. Physicians need better information regarding the therapeutic efficacy and equivalency of brand name drugs and generics. Patients need to be better informed about the variation in retail pricing of drugs and the role of generics in medical treatment.

To address these concerns, the Board of Trustees recommends that:

- The following policy statement be adopted:

  The AMA supports programs whose purpose is to contain the rising costs of prescription drugs, provided that the following criteria are satisfied:

  1) physicians must have significant input into the development and maintenance of such programs;

  2) such programs must encourage optimum prescribing practices and quality of care;

  3) all patients must have access to all prescription drugs necessary to treat their illnesses;

  4) physicians must have the freedom to prescribe the most appropriate drug(s) for the individual patient; and

  5) such programs should promote an environment that will give pharmaceutical manufacturers the incentive for research and development of new and innovative prescription drugs.

- Policy be reaffirmed supporting the freedom of physicians to use either generic or brand name pharmaceuticals in prescribing drugs for their patients and encouraging physicians to supplement medical judgments with cost considerations in making these choices.

- Physicians be encouraged to stay informed about the availability and therapeutic efficacy of generic drugs. The AMA should assist physicians in this regard by regularly publishing a summary list of the patent expiration dates of widely used brand name (innovator) drugs and a list of the availability of generic drug products.

- Expansion of third-party coverage of prescription pharmaceuticals as cost-effective and necessary medical therapies be encouraged by the AMA.

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Mr. **Waxman**. Thank you.

Ms. Rosenbaum.

STATEMENT OF SARA ROSENBAUM

Ms. **Rosenbaum**. Thank you.

We appreciate the opportunity to testify today.

No population has more at stake in this legislation than children on Medicaid. They are half of Medicaid beneficiaries. Medicaid represents 55 cents out of every public health dollar spent on children. About one-third of all the pediatric health care is through Medicare.

Minority children are two to three times as dependent on Medicaid as their nonminority counterparts, so they are particularly affected by the quality of and accessibility of Medicaid services.

We believe the bill introduced by Congressmen Wyden and Cooper, legislation introduced by Senator Pryor and the initial legislation introduced by Senator Pryor all have the continued potential to help Medicaid agencies save funding under this program.

We have been deeply disturbed over the past several months that persons who have spent little time thinking about the quality of medication for low income health services have now come forward to express concerns about the quality of Medicaid programs.

There is no place in Medicaid where we see the impact of the high cost of Medicaid on the quality of services than drugs. As early as 1976, the State of Georgia instituted a drug formulary program that was so unreasonable that it was struck down in court. If the Wyden-Cooper standards had been in place in 1976, the case would not have been brought.

We have seen State after State enact severe limits, restrict their formulary so life saving drugs could not be obtained. Institute mandatory substitution programs that prevent physicians from substituting drugs that are preferred drugs when necessary and impose fees so low that in many States there are large areas where there are no pharmacist available to Medicaid patients.

The Wyden-Cooper bill would significantly help not only by ensuring a rebate system but by combining a rebate program with expanded formularies and an adequate prior approval system.

Rebates alone will not solve this program. They must be combined with the formulary and prior authorization part of the bill.

First, we hope that the best price program can be extended to the handful of federally funded clinics providing health care and family services. Many of these patients are uninsured. We hope these clinics also get the benefit of best price.

Second, we encourage this committee to include in its bill a study of the pricing and availability of vaccines under Medicaid. It is unclear what price is being paid for childhood vaccines because they are not subject to the validation process as in prescribed drugs.

In some cases where 50 to 60 percent of all children in a community are on Medicaid, we are seeing levels of low as 50 percent. We think they are not providing providers with sufficient funds to cover reasonably priced vaccines.

We believe the issue of acquisition, pricing and availability is one that deserves further study.

Thank you.

[The prepared statement of Ms. Rosenbaum follows:]

PREPARED STATEMENT OF SARA ROSENBAUM, DIRECTOR, PROGRAMS AND POLICY, CHILDREN'S DEFENSE FUND

Mr. Chairman and members of the subcommittee, the Children's Defense Fund [CDF] appreciates this opportunity to testify before you today regarding the Medicaid Anti-Discriminatory Drug Price and Patient Protection Act of 1990. CDF is a national public charity which exists to provide a strong and effective voice on behalf of the nation's children. We pay particular attention to the needs of low income, minority and disabled children. For nearly 20 years CDF has engaged in extensive efforts to improve poor children's access to decent health care. Because Medicaid is the largest publicly funded health program for children, its scope and quality at both the national and state levels have been of the utmost concern to us.

As childhood poverty has increased and private insurance coverage of dependents eroded, the already considerable significance of Medicaid for children has grown further. In many states, Medicaid is now financing between 40 and 60 percent of all births, as well as basic health care for nearly half of all young children. The 1989 Report of the White House Task Force on Infant Mortality indicates that nearly half of all U.S. births annually are to families with incomes below 200 percent of the federal poverty level. Unless childhood poverty drops dramatically or Medicaid is replaced with an alternative program, then in the next decade we can expect the program to be a, if not the, primary third party health insurance payor in the nation for maternal and child health.

The quality, financial soundness, and accessibility of state Medicaid programs therefore are of prime importance to child health—indeed even more so than for older populations. Medicaid represents 55 cents out of every public health dollar spent on children, compared to only 25 cents of public funds spent on the elderly. Half of all Medicaid recipients are children, even though children under age 18 comprise only one-quarter of the U.S. population as a whole. Over two-thirds are either children or women of child-bearing age. As a result, the severe strains on state Medicaid budgets that are the subject of almost daily news reports hold disproportionately severe implications for poor women and children. Nearly every state Medicaid cutback has particularly grave implications for children, because Medicaid's maternal and child recipient population is so poor and without alternative forms of coverage.

The financial soundness and quality of state Medicaid programs is of particular concern to minority children. Black children are more than twice as likely as white children to depend on Medicaid for basic health coverage. Even among poor families that work, black children are more dependent on Medicaid and less likely to have access to employer-based coverage.

While CDF has been concerned over the years with expanding Medicaid to all the low income children and families who need it, we are equally concerned with the scope and quality of coverage for those children who receive assistance. Extending benefits that are inadequate or of poor quality is a meaningless exercise. Thus, we view with alarm the major cost pressures in the Medicaid program that have led states to control program expenditures by freezing or reducing eligibility, creating virtually insurmountable barriers to program enrollment or benefit retention, eliminating necessary benefits, freezing or reducing provider reimbursement to such an extent that care and services are no longer available, or otherwise administering their programs in ways that diminish, rather than enhance, Medicaid's capacity to play the critical role in child health which it is increasingly being called upon to fulfill.

The amount, duration scope and quality of benefits and services available to poor women and children under Medicaid is also crucial because of their greater health needs resulting from the greater prevalence of illness and chronic disability among low income children. Poor children are twice as likely to be born at low birth weight and almost twice as likely to suffer activity limiting impairments. These children need the very best care available, not services that are artificially constrained because of cost.

Unfortunately, however, many Medicaid agencies place stringent limits on coverage of essential benefits, including prescribed drugs. Strict limits on the number of different prescriptions which can be dispensed are common, as are formularies so limited that crucial drugs are entirely uncovered. Prior authorization systems that would discourage even the most dedicated providers from attempting to prescribe a preferred drug are common. Fees paid to pharmacies frequently are so low that it is not unusual to find entire low income communities without a single pharmacy participating in Medicaid.

Equally serious is the pressure placed by Medicaid agencies on providers to prescribe generic drugs in all cases—either because the brand name drug is simply not covered by the agency or because the procedures for obtaining clearance to prescribe and dispense a brand name drug is excessively onerous. In recent months a host of problems with generic drugs have come to light, ranging from the outright fraud used to obtain FDA approval to the less glamorous but very real problem of poor quality and ineffectiveness of generic versions of certain prescribed drugs, such as drugs used to control epilepsy. At the receiving end of these problems are the nearly 12 million children who depend on Medicaid.

For this reason we support any effort to responsibly reduce the cost of drugs as a means of promoting quality benefits and services under the program and reducing program reliance on those generic drugs which are less effective than their brand name counterparts.

As this Committee fashions prescription drug rebate legislation, we believe that the following considerations are essential both to ensure that savings made do not come at the expense of program beneficiaries and to strengthen Congressional efforts in this area:

(1) Be realistic about implementation timetables: The legislative proposals assume that, with narrow exceptions, prescribed drugs subject to the rebate program will not qualify for federal financial participation unless a valid rebate agreement is in effect. This means that large numbers of vital sole source and multiple source drugs could disappear from state formularies overnight if rebate agreements are not in place. While we certainly want to see savings made at the earliest possible time, administration of Medicaid is so complex at both the federal and state levels that a minimum implementation time period of nine months from the date of enactment is essential to protect against the wholesale collapse of state drug programs.

(2) Eliminate the use of an artificial price inflator: We are concerned that over time, an annual price inflator (particularly one that holds the prescribed drug "best price" increase to the annual CPI rate) may be so severe that drug companies will ultimately refuse to sell key drugs to state agencies. We believe that it is sufficient for the legislation to require companies to give state Medicaid programs rebates that equal their annual lowest negotiated purchase price offered any institutional purchaser without further locking the manufacturers' drug price increases into a base year price plus the CPI.

(3) Do not overly encourage the use of prior authorization: The legislation proposed would permit the prescribing and dispensing of any drug, whether or not a rebate agreement is in place, if the drug is preauthorized. Prior authorization systems are useful to control certain types of commonly abused drugs. But they also, even if modified as recommended by the legislation, add another layer of bureaucracy to a program already infamous for the difficulties it poses for providers. While all Medicaid programs should bring any prior authorization systems into conformity with the recommendations made in the bill, a prior authorization means for getting around the rebate agreements will potentially cause some manufacturers to avoid entering into such agreements and will force providers to go through an authorization process each time a common, non-abused drug is required. Instead we recommend that the legislation require the Secretary to identify all drugs without rebate agreements that state agencies must cover, regardless of whether an annual rebate agreement is in effect, because they are sole source drugs or because of their greater effectiveness.

(4) Require state Medicaid programs to cover all drugs for which a rebate contract is in place: An important aspect of this legislation is its potential to bring down the cost of both sole source drugs and innovator and non-innovator multiple source drugs whose brand name products are of superior quality. Once their price has been made more reasonable, there is no justification for Medicaid agencies' refusal to cover these drugs. While the legislation proposes to prohibit state Medicaid agencies from obtaining FFP for drugs for which there is no agreement that coverage will be complete for those drugs with rebate plans in effect.

(5) Exempt vaccines for the time being, but require a followup study of the adequacy of childhood vaccine programs under Medicaid: Although vaccines are drugs they are not prescribed and dispensed in the same manner as other drugs, since there is no separate acquisition cost plus a dispensing fee. Moreover, vaccine prices now also reflect the special taxes imposed by the national vaccine compensation system. Finally the federal immunization grants program is itself a bulk purchasing program which makes vaccines available at lower prices to state health and Medicaid agencies.

However, we do recommend that any legislation instruct the Secretary to study the issue of state Medicaid reimbursement for childhood vaccines and to determine whether changes are needed either in state coverage of vaccines or in the price which state Medicaid agencies pay for vaccines or in the manner in which vaccines are reimbursed.

Currently, many states pay no set purchase price for the vaccines used by Medicaid children but instead include an amount for the vaccine (not necessarily reflective of the vaccine cost) and its administration in their basic pediatric reimbursement rates. It is entirely unclear, therefore, whether the rates that state Medicaid agencies are paying are sufficient to cover even a vaccine's "best price"—that is, the lowest institutional price paid by either the Public Health Service or other public or private bulk purchasers. There have been repeated instances of vaccine shortages among Medicaid providers, who find that their reimbursement is insufficient for them to offer immunization services. There have also been several instances in which Medicaid HMOs have been found not to be vaccinating children (even though presumably the cost of vaccines and their administration is included in the plan's capitation rate), because the product is considered too expensive to maintain. It is also unclear whether every state Medicaid agency, under its EPSDT program, is covering a sufficient amount, duration and scope of childhood vaccines in order to meet the recommended immunization protocols of the Centers for Disease Control.

The U.S. now ranks 15th in the world with respect to the proportion of 1-year-olds adequately immunized against polio. When only black infants are taken into account—and black children are more than twice as likely to depend on Medicaid for basic coverage—the nation ranks 49th worldwide. It is essential that final drug purchasing legislation instruct the Secretary to study the issue of Medicaid coverage of childhood vaccines generally, and state agency pricing patterns in particular, so that further reforms can be legislated if necessary.

(6) Assure low drug prices for Public Health Service programs that provide care to the underserved: Thus far, all attention has been focused on a rebate system for Medicaid agencies. However, many of the nation's more than 600 community and migrant health centers and homeless health care clinics maintain extensive pharmacy programs for their patients—both patients with Medicaid and the 50 percent of all patients who are completely uninsured. Many of these providers have been particularly hard hit by the terrible cost of prescribed drugs and vaccines—so much so that their ability to furnish even basic medications to their low income and uninsured patients is seriously constrained. Additionally, however, a number of health centers have been able to secure significant reimbursement from drug manufacturers, in some cases lowering their price to a level even less than the level that will be paid by Medicaid under the legislation.

We therefore ask that in order to ensure low prices to health centers serving the underserved and to avert what otherwise would be a major cost-shift to these providers, the Committee bill include a special rule for grantees under Section 329, 330 or 340 of the Public Health Services Act. That rule should specify that in the case of drugs purchased by such grantees the best price will be the lower of either the best price paid by the Medicaid agency as defined under the Act or the actual price paid by the grantee on September 1, 1990.

Mr. WAXMAN. Thank you very much.

Mr. Wyden.

Mr. WYDEN. Mr. Mossinghoff, let me begin with you.

With what your companies have overcharged Medicaid during 1980, millions of low income families could have received health care. All through the 1980's there were cutbacks for everybody else, cutbacks for the low income people, cutbacks for the providers, the doctors and hospitals, but your people just keep stiffing Medicaid and giving discounts to the large buyers, the HMO in town or the VA, or whoever.

Now, you have come today to basically say, Ron Wyden and Dave Pryor and others want to review access to health care. We have already made changes in this bill. There is no therapeutic equivalences. There is no therapeutic substitution.

Manufacturers who offer discounts to Medicaid would be guaranteed that all their drugs would be included in the State formulary.

There is open access now. I just don't understand how you can come in and in good faith make this a big scare about how we are reducing access. In fact, even in the prior approval area where you focus today, we don't do anything to increase prior approval. The only thing we do is make it less restrictive by saying if a State has a program we are going to require that it be accessible to physicians 24 hours a day, 7 days a week.

On this question of prior approval where you have raised a big new scare today, show me one thing in our legislation, one thing which increases the prior approval requirements that are on the books today.

Mr. MOSSINGHOFF. Mr. Wyden, I don't know if there is anything that increases them.

Mr. WYDEN. Of course, there is not.

Mr. MOSSINGHOFF. If your intent in drafting this bill is to carry out what you said in your statement, namely that anybody who provides a discount or a rebate has their drugs on the formulary without prior approval, we know how to help you write that.

The way it is written, even though the manufacturers would give a substantial discount, the State would not have the prior approval.

I applaud that it is 24 hours a day, 7 days a week telephonic. Hospital on the other end of the line; hospital on the other end of the line might say no. Then what happens, the drug is simply not available.

I understand that is the concern of someone this morning. Somebody said no, it has to be half dosage, not full dosage. The criteria for prior approval is not here. Even the qualifications is not in the bill. There is no appeal or dispute procedure. It is simply if the other person on the end of the lines says no, the answer is no. That is a limitation on access.

Mr. WYDEN. I will repeat the question.

Show me one thing that increases the prior approval requirements. States have their own criteria, as you know, on prior approval. The only thing we are trying to do is roll it back. You have come in and created a scare about prior approval. I would like you to show me one thing that increases prior approval. The only thing we have done is roll it back.

Mr. MOSSINGHOFF. You have provided a laudable procedure, telephonic, 7 days a week to permit the same very burdensome prior approval systems.

I submit if a manufacturer is providing deep discounts as they are in the States under negotiations now and the State is providing those discounts then that drug should be available as it is now in the States. Anything less than that rolls back the successes that are occurring.

The enormous coalition we put together in opposition to S. 2605 and the OMB proposal for negative therapeutic substitution, that coalition is very concerned about having access to all drugs. If the manufacturers do provide the rebate that you have in the bill, it seems to me we would hope the subcommittee would question providing a quid pro quo, providing the other side, namely, make that drug available.

That is what is happening in the States. The legislation would interrupt a beneficial trend that is happening now.

Mr. WYDEN. Do any of your companies require repeal of prior approval in a State to give a discount?

Mr. MOSSINGHOFF. Perhaps Mr. Zabriskie can answer.

Mr. ZABRISKIE. As I said, we have been very successful in getting our program accepted by a great many States, 32 formularies and 10 are on record that they are going to do so.

The way our system works is that in exchange for our best priced discounts, the States put our products on formulary without prior approval.

I think the point Mr. Mossinghoff was making, Congressman, was that this provision in your bill is sort of a step back from something we have achieved.

Mr. WYDEN. The point is, in a lot of States in this prior approval issue, they don't even answer the telephone. Both of you know that. That is the reality about prior approval programs.

The only things our legislation says is you have to be there 24 hours a day, 7 days a week.

Mr. Mossinghoff misrepresents the impact of this bill. If you want to come in and say that it did not perfectly deal with the issues of prior approval, no quarrel there, because we don't do that.

What you have tried to do is paint another scary picture that we are reducing access by increasing prior approval requirements. That is misrepresenting what is going on.

Mr. WAXMAN. The gentleman's time has expired. I am sure you will have an opportunity for a second round.

Mr. NIELSON. Mr. Ziegler, I would like to ask you why do the pharmaceutical prices vary among purchaser? You have the same costs. Why do you have different pricing structures?

Mr. ZIEGLER. The different pricing structures at the retail levels?

Mr. NIELSON. Yes, why can one purchaser get them for a different price than other ones?

Mr. ZIEGLER. In the retail market place, competitive factors control to the total extent the prices we charge for prescription drugs.

Mr. NIELSON. Do you have a different set of contract items?

Mr. ZIEGLER. There are 30 contracts that exist.

Mr. NIELSON. Are they based on cost or volume?

Mr. ZIEGLER. On a number of criteria depending on the program that the third party is putting forth and the scope of the universe.

Mr. NIELSON. Are they very worthy groups such as Veterans' Administration or other groups?

Mr. ZIEGLER. I am addressing the retail side of the equation.

We don't deal with the Veterans' Administration.

Mr. NIELSON. But you charge different prices to different customers, individuals, HMO's, Medicaid, others.

Mr. ZIEGLER. The Medicaid reimbursement caps are established by each State. The retail pharmacy has senior citizen discounts that are very widespread in the chain drug store industry that we provide at the retail level. I don't know how to get to an answer to your question beyond that.

We give discounts to senior citizens and we give discounts based on the business decision of a community pharmacy.

Mr. NIELSON. Based on the decision of how worthy the individual is, like the Veterans' Administration is more worthy than Medicaid, why do you charge different prices to different customers, chain store level and pharmacies in general?

Mr. ZIEGLER. The basic competitive factors in the market place control retail prices. That is what you pay when you go into a community drug store. If you happen to fall into the category of senior citizen one day——

Mr. NIELSON. I am 66. I do.

Mr. ZIEGLER. Then many drug stores will give you a discount. Those are the two basic prices. The Medicaid amounts that we received under the Medicaid program are determined by the Medicaid program. I think it is worthwhile to point out that the Medicaid reimbursement caps are under limits established by the program for retail pharmacy, 85 percent of the prescriptions that we fill for single source drugs are billed and paid at "usual and customary" which is below the cap standard for a single source drug.

Mr. NIELSON. Mr. Ingram, why are the prices different?

Mr. INGRAM. We have different prices. I think it basically reflects the reality of the free market.

As I referred to in my statement, the Veterans' Administration will receive our lowest discount.

Mr. NIELSON. Why?

Mr. INGRAM. Really an analogy of history.

Mr. NIELSON. Is it because they are more patriotic?

Mr. INGRAM. It reflects the fact that they buy large quantities. They warehouse and dispense our product.

Mr. NIELSON. So it is based on the service they provide to take some of the problems off your hands; is that it?

Mr. INGRAM. Yes.

Mr. NIELSON. Dr. Bristow, do you consider it a requirement for prior approval to get a prescription? That was asked by Dr. Rowland of Representative Cooper. I did not understand his answer.

Mr. BRISTOW. The question being do I consider prior authorization necessary?

Mr. NIELSON. Yes.

Mr. BRISTOW. Yes, sir, I do.

Mr. NIELSON. Do you think prior approval should be used by the States at all?

Mr. BRISTOW. To be quite honest with you, well, let me tell you where I am coming from.

I believe all patients should have access to those medicines they need for their medical condition.

Mr. NIELSON. Without prior approval?

Mr. BRISTOW. Without being prohibited because of inability to pay.

So I say prior approval should not be part of this process.

The only area in which I would find it conceivably acceptable would be if one were using it as criteria for determining authorization, those criteria used in the three pharmaceutical compendia we are discussing today.

Mr. WAXMAN. The Chair recognizes himself for 5 minutes of questioning.

Mr. Parks, you testified that California had negotiated discount contracts with two of the contracts represented in the table: Merck, Sharp and Glaxo. Each has its own proposal for Federal legislation which reflect differences in calculating the amount of the rebate.

In which of these contracts did California save more, the American contracts or the Glaxo contracts? Do these contracts reflect the differences in calculating rebates that the manufacturers are urging here today?

Mr. **Parks**. I have to be careful how I answer the question.

Because of part of the State law did provide for confidentiality of negotiated contracts, I think I can, however, give you an answer that may get you part of what you want to know.

First of all, the amount of discount available to a State Medicaid agency is going to vary from company to company depending on a number of factors. One is the depth of the company's pricing policy. In other words, what is the difference between the average manufacturer's price and their best price.

For a company with a small spread, that is going to be a factor. Some companies have spreads of less than 10 percent and others have spreads of over 40 to 50 percent. We have been successful in many cases in getting best price in some cases and in other cases what we consider acceptable price which sometimes for one company will be a greater spread than for another company.

Mr. **Waxman**. As I understand it, there are five States that have formularies with substantial restrictions on drugs: California, Kentucky, West Virginia, Mississippi, and Alabama.

In these States, Medicaid beneficiaries have access to drugs that States have excluded from their formularies. California kept three FDA-approved breakthrough drugs off the formulary for 6 years, another for 3 years and 18 months respectively.

I can understand if you are paying ultra high prices why you would want to exclude coverage but under this bill you will get discounts on all drugs. Why would you continue to keep FDA-approved drugs off your formulary?

Mr. **Parks**. As a result of the contracts we have been able to agree to so far, we have added 215 drugs to the list. We included in our State legislation a commitment to include all drugs rated by FDA as 1–A drugs.

From my perspective, I would have to agree. If we were able to get those discounts, we have an obligation to assure that those drugs that represent significant breakthroughs be available through the medical drug formulary. We have made that commitment.

Mr. **Waxman**. Mr. Zabriskie, I want to commend you and your company for recognizing Medicaid has a problem here and taking the initiative in the market place and also here in the Congress to develop a responsible alternative. I hope the rest of the industry will follow your lead.

My question goes to the Wyden-Cooper provision that would index the best price to the consumer price index. I understand the purpose of this provision is to assure over time the amount of the rebate for Medicaid does not decline as drug prices increase. Apparently, the cost estimate forces are concerned about that possibility.

Do you have an alternative?

Mr. **Zabriskie**. On principle, we are opposed to the indexing of prices. I understand that the index provision is in the bill because of the concerns that you have raised and in order to get a passable bill.

From Merck's point of view, an approach might be in our proposals that there is a minimum 10 percent discount that, in aggregate, would always have to be given to the Medicaid system. So the minimum rebate would be 10 percent.

People have argued that that 10 percent could be quickly eroded if the manufacturer were to increase prices faster than the consumer price index.

Merck believes that a way to handle that situation would be to increase the discounts should a manufacturer increase prices faster than the consumer price index by an amount of the excesses over the consumer price index such as the discounts to Medicaid would get larger.

Mr. WAXMAN. No one was talking about indexing the prices. We just want to be sure we get the discounts.

Mr. ZABRISKIE. That is right. This would allow you to get the discounts but prices would not be indexed.

The best prices are the retail prices. I hasten to add that that is just Merck's position.

Mr. WAXMAN. Thank you.

Mr. Bliley.

Mr. BLILEY. Mr. Mossinghoff, can you comment on the auditing system contained in the Wyden bill? Do you believe the auditing is sufficient to discourage the fraud that often accompanies these programs?

Mr. MOSSINGHOFF. Mr. Bliley, we have only had the bills for 2 or 3 days, so we really have not had a chance in detail.

Mr. BLILEY. The records will be open.

Mr. MOSSINGHOFF. Let me respond. This is anecdotal. This is based on conversation with people in the industry.

There were discount provisions several years ago, and there was a serious question, I am told, in the industry, on the auditing or the recordkeeping of actually what drug was dispensed, particularly I think difficult in the generic area, and we would be willing to work with the committee to see if there is some way if legislation is enacted to make certain the drug said to be dispensed is the actual drug dispensed.

It is fraught with problems in terms of scoring and recordkeeping.

Mr. BLILEY. Since the Wyden bill appears to call for an open formula, why do you equate a 24-hour preapproval system with a formulary?

Mr. MOSSINGHOFF. I think the major thing is the bill has praiseworthy procedures. It has no substance in drugs where you could have deep discounts—as the bill is written, you would have a deep discount indexed to the CPI. The manufacturer would be doing everything the manufacturer should do, and yet, on a prior approval system, the answer on the other end of the line could be no, and we think that is inappropriate. It is a step backward from where the companies are working now.

Mr. BLILEY. Would there be an appeal process?

Mr. MOSSINGHOFF. What happens now, if you have a discount, your drug is on the formulary and the patient can get it. Under the

Wyden-Cooper bill, if you give a discount, the drug may or may not be on a formulary and the patient may or may not be able to get it, depending on what the answer on the other end of the line is.

Mr. BLILEY. Is there any appeal?

Mr. MOSSINGHOFF. We would agree with the AMA, we would agree if it were limited—if all drugs that were in the three major compendia, if that is a limitation, I think PMA would sign up right now. The drug has to be in the compendia for accepted medical use.

An arbitrary no on the other end of the line seems to be less beneficial to patients than the current situations that are being negotiated.

Mr. BLILEY. Is there a way to score the programs from the savings which many of your companies have offered the States?

Mr. MOSSINGHOFF. I am no expert on how you score things during a budget summit. I understand the Congressional Budget Office says, based on what has been done already, there are hundreds of millions of dollars of savings in the program.

That is going to be reflected in base line, since a lot of those savings occurred in fiscal year 1990 and they are not scored in 1991, 1992 and 1993. If you were certain about what would happen in all of these scorings, if you were certain about it, you wouldn't need actuaries, you would have to prove it.

Seems to me what is happening now is readily scorable in the real economic sense as anything that would happen under the bills.

Mr. BLILEY. Do pharmaceutical manufacturers support drug utilization review?

Mr. MOSSINGHOFF. We have been since I have been at PMA. We have two caveats. We don't want to see it interfere with the patient-physician relationship or introduce a hassle factor which is on one drug as opposed to another drug. We don't want to see DUR being changed in some sort of formulary, but recently DUR, PMA would support.

Mr. BLILEY. Thank you.

Mr. Rector, what do you think would be fair percentage of profit versus your cost on Medicaid prescriptions?

Mr. RECTOR. At the retail level?

Mr. BLILEY. At the retail level.

Mr. RECTOR. Our general protection profit for retail across the board is just under 3 percent. That includes Medicaid business where a pharmacy, as Mr. Ziegler indicated earlier, retail pharmacy, is losing a substantial portion on every Medicaid prescription. I don't know the exact—but I know we are generally just under 3 percent, and Medicaid would be somewhat less than that, given the situation with Medicaid.

Mr. BLILEY. May I follow up for 10 seconds, Mr. Chairman? The record will be open for some time. Would you get your folks to look at that and see if you can't come up with a number and furnish it to the committee?

Mr. RECTOR. Certainly.

Mr. BLILEY. Thank you.

Mr. WAXMAN. Mr. Wyden.

Mr. WYDEN. Mr. Mossinghoff, let me ask you the question about the multiple source drugs at this point. None of the company proposals include discounts for these innovative multiple source drugs, the brand-name drug for which the patent has expired and generic competition exists.

In our analysis, we found Medicaid is often paying a great deal more for these drugs, as well in relation to the private payers. For example, Endoral, a common drug, Medicaid pays 40 cents, the Veterans' Administration pays 6 cents, a difference of over 500 percent.

Why shouldn't Medicaid get a discount on these multiple source drugs as well?

Mr. MOSSINGHOFF. Mr. Wyden, I don't think we would at all oppose discounts on multiple source drugs. A point in my statement—and indeed the Pfizer proposal, which is described in a brief attachment to my statement, does provide, I think, three different ways for that issue to be addressed.

One is a discount, and I believe the other is competitive bidding among multiple source drugs. What we do find vary, vary almost punitive in nature is the fact that the U.S. manufacturer, an innovative manufacturer doing exactly the same as a noninnovator company, namely making and selling a multiple source drug, is disadvantaged in this bill compared with the generic competition.

We submit, if it is a multiple source bill—there are already regulations throughout the country in Medicaid and each State that says, unless the doctor writes in his own hand brand-name medically necessary, that the generic product and a multisource product is dispensed.

We think because someone happened to invent this new drug, we don't think they should be disadvantaged over someone who merely copies that drug.

Mr. WYDEN. Let me save a little time. I don't think, for example, Mr. Ingram, Glaxo's proposal includes multiple source drugs. It is the position, then, today, Mr. Mossinghoff, of the PMA, you should be able to get discounts for multiple source drugs in a procedure along the lines which you described?

Mr. MOSSINGHOFF. As long as it is a fair approach and treats multisource the same.

Mr. WYDEN. Let me ask you about the question of R&D. I have seen a great many statements by the PMA that would indicate the kind of legislation that we are talking about would lessen the value of patents, make pharmaceutical research less attractive to investors, but we have also got an analysis from Kidder Peabody, their equity research department, indicating this bill would be immaterial in terms of its impact on research and profitability.

Can you explain the difference in opinion between a major economic forecaster and what your companies are saying?

Mr. MOSSINGHOFF. Mr. Wyden, you have not seen, I respectfully submit, any statements by PMA on what effect your bill would have on research and development in the pharmaceutical industry. We don't know what—what you have seen on your bill was included in my 6-page statement, and those are all we have. Those are the only PMA policy statements on your bill.

Mr. WYDEN. We have an opportunity to make progress, then. Are you saying my bill, the new bill with Mr. Cooper that Senator Pryor has introduced, would not have a detrimental effect on patients and pharmaceutical research?

Mr. Mossinghoff. I am not prepared to say that, either, Mr. Wyden. I would say there are pretty definitive statements every $100 after tax capital to a company that amounts to about $35-plus that will not be done on research and development, but we have not had time to look at this bill.

If discounts like the Veterans' Administration discounts are indexed, I don't think there is any question it would have an adverse effect, but we have not said that yet, because we have not had a chance to look at it.

Mr. Wyden. What is interesting, major economic analysts like Kidder Peabody have written memos indicateing that the more restrictive Pryor bill would have no detrimental effect on the drug industry.

Our legislation, particularly the changes we talked about today, seems much more generous, and I hope that you will conclude that this does not have a detrimental effect on the industry.

I think what I would like to do now, because time is short, is go down the row and see if we can get the position of the major organizations.

I know some of you are not set up so you can endorse a specific bill, so let us, if you can't endorse the bill specifically, let's talk about the concepts.

Ms. Rosenbaum, does your organization endorse the new legislation or concepts introduced now on the House and Senate side?

Ms. Rosenbaum. Yes, we support the legislation.

Mr. Wyden. Dr. Bristow, I know your process is very involved, but in terms of the concept, do you all support the new legislation?

Mr. Bristow. As you pointed out, we are in the process of giving a thorough evaluation. We are pleased to see there is no therapeutic discussion involved in this bill. We are pleased to see Congress address an economic problem which attempts to bypass an impact on patients.

We do have specific concerns we hope we can work out with you, and we are looking forward to that effort.

Mr. Wyden. Mr. Gans.

Mr. Gans. We support the bill, and we support the initial Pryor legislation.

Mr. Wyden. Mr. Rector.

Mr. Rector. We have specifically endorsed the Wyden-Cooper bill, as well as the new S. 3029.

Mr. Wyden. Mr. Ziegler.

Mr. Ziegler. As I said in my testimony, strongly support many of the concepts of the Wyden-Cooper bill and Pryor bill. We have very strong reservations about the prescriptive elements contained in the Pryor bill on consultation, not DUC, but consultation.

Also, we feel strongly if we really are going to get this, we urge you to consider our request for the reimbursement section to be contained in your bill.

Mr. Wyden. If you next three support it, I will ask the chairman to adjourn.

Mr. Ingram. I think we may be here. I think, as Mr. Parks stated earlier, Mr. Wyden, we at Glaxo see in California and other States that the current situation is working in terms of companies like Glaxo and others negotiating better prices for the Medicaid system.

We would encourage that you consider, in place of perhaps this legislation, a directive to the States that would ask them to report back to you at a point in the future that you determine as to how has the performance of the industry been in that regard.

Mr. Wyden. Mr. Zabriskie.

Mr. Zabriskie. Mr. Wyden, I support what my colleague has just said here. However, should Congress decide a piece of Federal legislation is indeed necessary, I think America would support the concepts that you have put forward.

On the other hand, we do have some serious reservations we would like to continue to work with your staff on to see if we can come to some agreement with a bill that we could support fully.

Mr. Wyden. Mr. Mossinghoff.

Mr. Mossinghoff. I think of the totally uneven effect of the bill would have on people that have done things lawfully and appropriately, that PMA would be forced to oppose the bill on that ground and oppose it vigorously on the grounds it is interrupting State negotiations going on now, and you and I have had a good understanding.

I think there is a problem. This does permit openended approval systems to remain in place. So, we would oppose it as it is now written.

Mr. Wyden. Mr. Parks.

Mr. Parks. I guess I have to qualify the answer. We support the concept of drug discounts. We do, as I mentioned earlier, have some concerns relative to the potential requirements for requirements for eliminating or significantly modifying States' abilities to have a formulary and some of the other elements may have potential costs.

I would, if I could, like to take this opportunity, however, at great risk here to take exception to a couple of comments that have been made. I would like carefully——

Mr. Waxman. Excuse me, Mr. Parks. We don't have an opportunity for members to take exceptions and additional comments. Mr. Wyden was permitted to go over the 5 minutes to get a quick response. We will be pleased to receive comments from you in addition for the record.

Mr. Wyden. Thank you, Mr. Chairman.

Mr. Waxman. Mr. Nielson.

Mr. Nielson. Mr. Rector, you sort of criticized the drug industry of multitiering prices. I notice some pharmacists accept $1.92 as a dispensing fee from HMO's and charge other customers much higher fee. Isn't that multitier?

Mr. Rector. With regard to the industry's multitier pricing, I think the basic difference is the radical nature of the discrepancies in price. In any retail setting, you have different prices. I noticed in The Washington Post last week, there is an article about price gouging with gas. The price of 89.3 cents versus 95.3 cents per gallon, that is perceived in the oil and gas as price gouging.

We are talking about differences that range on the one hand from perhaps $3 on the one hand to $40 on the other hand. We certainly have, as alluded to earlier, discounts for senior citizens. I think we will continue to have those.

Mr. Nielson. You are also discounting for HMO's? Aren't you charging $1.92 for dispensing fees?

Mr. Rector. We would be happy to assess the particular circumstance you are referring to. I am not familiar with it.

Mr. Nielson. Okay, it is probably not clear to many people in the country there is a difference in pricing in the pharmaceutical area.

Mr. Rector. If there is—there is the bill pending in the Judiciary Committee, Chairman Brooks' bill that would eliminate the McCarran-Ferguson business with price fixing in the insurance industry, and certainly we have a number of contracts where we have no choice at all as to what the level of reimbursement will be, but we have no choice but to accept those contracts, and if we can get the clarification and repeal of the price fixing exemption for the insurance industry for those contracts, I think you would see more of a normal marketplace behavior even in the small discrepancies I think that you are asking about.

Mr. Nielson. Well, I think there is quite a large discrepancy. Sometimes a very large markup in the pharmacies on Medicaid drugs.

Mr. Rector. We would be happy to supply for the record a range of the markups at retail and compare them at great length to the markups of actual cost of manufactures and submit them for the record.

Mr. Nielson. Since many customers feel the dispensing fee you charge is your payment for handling the drug, what would be your reaction for raising the dispensing fee but reimbursing the pharmacy for his actual cost? What is your reaction to that?

Mr. Rector. In an interesting way, I think you described what the Health Care Financing Administration has done in the last several years when they have cut back our reimbursement under our current price controls cutback on beneficiaries and avoided addressing the true source of the escalation of price in the Medicaid program.

You come fairly close to describing our circumstance, that is why we are losing $300 million a year.

Mr. Nielson. You don't react well to that?

Mr. Rector. We strongly oppose that.

Mr. Nielson. Would you check also on this $1.92 as a fee for HMO's? I think that is fairly well-established in some pharmacies. It is well below what it should be.

Mr. Rector. I think once we get the pricefixing behavior, we move from the insurance industry and the intermediaries that negotiate our contracts, you will see fewer discrepancies.

Mr. Nielson. One of you said you did not oppose the medical approval program or drug utilization review. Was that you, Mr. Zabriskie? Could that be used to pressure doctors into making therapeutic substitutions?

Mr. Mossinghoff. That was one of our concerns. We would not support a drug review. If they interpose the review between the patient and physician relations, should be opposed.

Mr. **Nielson**. Would there be a possibility of forcing doctors to give a suboptimal prescription?

Mr. **Mossinghoff**. If misused, it could have that result.

Mr. **Nielson**. I ask Dr. Bristow the same question. Could a drug utilization review pressure doctors into prescribing something they don't think is as good, because of that process?

Mr. **Bristow**. It is therapeutically possible. That is one of the reasons we are concerned such a policy would be very carefully crafted. We would support the idea drug utilization should be reviewed to make sure the patients get the best medication and it is provided to them properly, but that should be done with physician input and crafted very carefully.

Mr. **Nielson**. Is there a way you could help us?

Mr. **Bristow**. We would be delighted to.

Mr. **Nielson**. You don't oppose the drug utilization review? You don't want the pressure on the doctor?

Mr. **Bristow**. That is correct. One thing that would be required is an effective appeals mechanism so the physician could object to that review.

Mr. **Nielson**. Thank you, Mr. Chairman. Thank you, panel.

Mr. **Waxman**. Thank you, Mr. Nielson.

Gentlemen, we appreciate your testimony. Let me close by giving you my observation that it looks quite likely this summit is going to propose to us to adopt a measure dealing with this very subject.

Mr. Mossinghoff and others in your industry, what we would like to have you do, rather than appear to be stonewalling, I would suggest if you—it would be much more helpful to us, and I think to your industry's interest in this issue if we could get your support and technical expertise in assisting the subcommittee to develop a responsible solution.

I thank all of you for your input on this issue. That concludes our business for the day.

[Whereupon, at 3:45 p.m., the hearing was adjourned.]

[The following material was submitted for the record:]

Affordable
Financing for
Long-term Care
A Public Private Partnership (518) 473-7705

BACKGROUND INFORMATION ON THE NYS/RWJ PROJECT:

LONG TERM HEALTH CARE FOR THE ELDERLY

Purpose:

- To design a more rational approach to LTC financing that will permit consumers to protect themselves against the high cost of LTC services, thereby encouraging self-sufficiency and decreasing reliance on Medicaid as the primary payor for LTC expenditures.
- Reexamine the fiscal roles of those paying for care and to design a better system to finance LTC services.
- Avoidance of impoverishment among elderly families by guaranteeing asset and income protection.
- Saving of State and Federal Medicaid funds which would otherwise be spent on individuals who did not have this incentive to purchase LTC insurance.

Current System:

"Medicaid is serving as the nation's LTC safety net. But some LTC advocates argue that it works as a self-fulfilling prophecy, forcing people into poverty to qualify for benefits. Nationwide, 43% of all Medicaid funds go for nursing homes, squeezing other health services for the poor." (Newsweek, March 12, 1990)

"A growing number of experts say that a mix of private and public coverage makes the most sense, economically and equitably. Any government plan is certain to mean higher taxes, and read my lips resistance from the White House." (Newsweek, March 12, 1990)

Program Features of NYS Demonstration Project:

- Minimum dollar coverage for each day in a nursing home representing significant economic protection; a lower daily benefit for home care;
- Inflation protection;

- 3 year coverage for nursing home care, or 6 year home and community-based care, or a combination of the two;
- Guaranteed renewability;
- No requirement for prior hospital or nursing home stay;
- Payment for care provided in certified nursing home or by licensed home care provider of patient's choice;
- Care management; and
- Open only to residents of New York State at time of purchase.

Accomplishments to Date:

- Model under design; implementation awaits a Congressional waiver;
- Carrier negotiations creating a quality product;
- Waiver provision passed in U.S. Senate; and
- State authorizing legislation passed in 1989.

Waiver

A waiver is needed from the U.S. House of Representatives to allow the use of Medicaid funds without the requirement of spenddown of income and assets for those people who purchase a private insurance policy under this demonstration project.

When the waiver is enacted by Congress and the NYS Dept. of Insurance fully reviews and approves these policies, they may be available as early as 1991.

How NYS/Federal Government will Save:

Private insurance can reduce the role of Medicaid as a source of payment for middle-income elderly by delaying or avoiding the need to spenddown their resources. People will have a viable alternative with the NYS plan that is more attractive than either transfer of assets or spenddown to poverty. People with sufficient assets to transfer can afford a policy to protect them, but cannot afford a long term stay in a nursing home at rates averaging over $45,000 per year today.

STATEMENT OF THE AMERICAN PSYCHIATRIC ASSOCIATION

The American Psychiatric Association, a medical society representing more than 36,000 psychiatrists nationwide, appreciates the opportunity to submit this statement on Medicaid reimbursement for prescription drugs.

The APA acknowledges the rapid growth in Medicaid expenditures on prescription drugs, but will to confine our comments for this hearing to one aspect of current Medicaid drug proposals: therapeutic substitution.

The Medicaid prescription drug program is an optional benefit for which a federal match is made. Although the drug program is not a "basic medical service," all 50 states provide some type of outpatient prescription drug benefit in addition to covering drugs prescribed incidental to hospitalization of a Medicaid patient.

The Congress may consider a proposal which would require some sort of therapeutic substitution of prescription drugs. This is currently embodied in a proposal developed by the Office of Management and Budget as part of the ongoing budget deficit "summit" negotiations between the White House and the Congress.

Under the Office of Management and Budget proposal, the Secretary of Health and Human Services would be required to designate one or more drug formularies to be used by state Medicaid programs to determine therapeutic substitution. A single national formulary would be established by 1992. States would be required to negotiate the "best price" for one or more drugs in each therapeutic class. These drugs would become the "preferred drug" for purposes of Medicaid reimbursement.

Once the preferred drug was established, pharmacists would be required to substitute the preferred drug for a named non-preferred drug unless the physician had specified on the prescription form, and in a method approved by the Secretary, that the the prescribed non-preferred drug was "medically necessary."

The APA is deeply concerned that therapeutic substitution proposals -- however carefully constructed -- would jeopardize the quality of health care for an already vulnerable group of Americans. While we recognize concern in some quarters about the rapid growth in federal and state expenditures on prescription drugs under the Medicaid program, we believe that therapeutic substitution is not an acceptable cost containment alternative.

The OMB proposal is particularly troubling. In addition to requiring the implementation of a national formulary, the proposal would also require pharmacists to substitute the "preferred" drug except where the physician had clearly specified (in a form specifically approved by the Secretary) that the non-preferred drug was to be used. Such mandatory substitution would take place without the knowledge of the physician or patient.

It is important to appreciate the legislative "spin-control" inherent in use of the word "preferred." Let us be clear and understand that the "preferred" drug is not necessarily therapeutically preferred but economically preferred. It is not what the patient and his or her physician prefer based upon medical need but rather what is in the payor's economic interest. As a matter of prudent medical management, we believe that an automatic substitution without notification to the physician is a direct and economically-driven interference in the practice of medicine by psychiatrists or any other physician. This automatic substitution of one drug for another may potentially reduce Medicaid outlays, but it also runs the risk of causing severe harm to the patient.

For example, a patient presenting with depression would be a candidate for any of the tricyclic antidepressants, such as imipramine, elavil, norpramin or desyrel. While any of these drugs within the so called "class of drugs" concept could be prescribed for the management of depression, each of the drugs has specific side effects which could contraindicate its prescription for a specific patient.

As an example, some tricyclics have a high degree of cardiotoxicity. It could be catastrophic for a therapeutic substitution of a potentially cardiotoxic drug for a drug such as desyrel which had been specifically prescribed for an older patient suffering from heart arrhythmia precisely because desyrel had a low degree of cardiotoxic effects. But it is highly plausible that such a "therapeutic substitution" could take place under the regime proposed by OMB, and the patient and the prescribing physician would be none the wiser.

The APA also is troubled by the OMB proposal's grant of outright immunity to pharmacists for liability under all state and federal laws for any damanges arising from a substitution made in accordance with the national formulary. No such protection would be granted to the the prescribing physician, whose instructions could be changed without notification. As such, the proposal exposes Medicaid patients to considerable risk, accords them second-class health care status while at the same time providing immunity to the very people -- pharmacists -- who are entrusted with the responsibility for the therapeutic substitution. This system cannot help but promote economic rather than clinical considerations.

The OMB proposal should be deemed unacceptable to the Congress and rejected if it is put forward as part of the budget summit agreement.

Mr. Chairman, the APA does understand the concern of the Congress and the White House about increased federal and state outlays for prescription drugs under the Medicaid program. However, proposals which -- at their core -- would place significant emphasis on economic incentives to use one drug over another have the potential for serious health consequences to patients, and, in the instance of the OMB proposal, would not even give the prescribing physician the opportunity to intervene on behalf of his or her patient.

The APA urges your Subcommittee to carefully consider the problems posed by therapeutic substitution proposals, and hopes you will act to ensure that the best interests of economically vulnerable Medicaid patients are not sacrificed on the altar of deficit reduction.

Statement for the Record
# of the
California Children's Hospital Association

The California Children's Hospital Association ("CCHA") appreciates this opportunity to submit these comments for the record of the Health and the Environment Subcommittee's September 14, 1990 hearing on Medicaid managed care issues. CCHA is a nonprofit organization comprised of the seven children's hospitals in the State of California which is dedicated to improving the health of all children. CCHA hospitals provide a substantial amount of the tertiary and secondary care to children in California. CCHA members are high volume providers of Medicaid services for very sick children.

I. Introduction

Mr. Chairman, as we all are keenly aware, ever-increasing health care costs are putting an enormous strain on this country's health care system. Predictably, this situation has led to sustained efforts to constrain health costs. In the Medicaid program, this has been reflected in states' growing interest in prepaid health plans as a way of controlling unnecessary utilization and containing Medicaid costs. In the Omnibus Budget Reconciliation Act of 1981 ("OBRA '81"), the federal government gave states the option to use HMOs and other prepaid health plans as a way of attempting to control Medicaid costs. According to the General Accounting Office ("GAO"), as of December, 1987 Medicaid enrollment in HMOs and other prepaid health plans had grown to over 1.1 million. Undoubtedly, states' interest in managed care options will continue to grow during the 1990's.

While we acknowledge that managed care plans will likely play a larger and larger role in both private and public health programs, CCHA has a number of concerns relating to the impact of Medicaid managed care plans on sick children needing specialized services. Simply put, the financial incentives fundamental to managed care plans inherently conflict with timely access to specialized care services. Based on our experience in California, we have the following concerns about such plans:

- reduced beneficiary choice;
- reduced access to early diagnosis and appropriate treatment; and
- inadequate reimbursement rates.

II. Experience with Health Insuring Organizations in California

These concerns are based in large part on our experience in California with county-based health insuring organizations ("HIOS"). In the Spring of 1983, the State of California began operating two county-based HIOs in Monterey and Santa Barbara Counties under Section 1115 demonstration waivers. These HIOs, managed by public agencies established by state law, were responsible for arranging for all Medi-Cal covered services for all Medi-Cal beneficiaries within their counties. Eighteen months later, the HIO in Monterey County was terminated due to financial insolvency. The Santa Barbara HIO (the "Santa Barbara Health Initiative", or "SBHI"), while having experienced some financial difficulties over the past five years, continues to operate under its Section 1115 waiver. Later, the State applied for a Section 1915 waiver to establish an HIO in San Mateo County (the "Health Plan of San Mateo", or "HPSM"). This HIO became operational on December 1, 1987 and continues in existence today. The HPSM and SBHI operate exempt from the following Medicaid requirements: (1) that Medicaid beneficiary enrollment not exceed 75 percent; and (2) that beneficiaries be allowed to disenroll freely with one month's notice.

Last year, the House budget reconciliation legislation contained a provision which would have allowed up to three additional county-based HIOs in California to operate exempt from Medicaid requirements. CCHA is very concerned about the possible negative effects resulting from such a proliferation of county-based HIO plans. In addition to concerns surrounding the historical ability of the HIOs in California to remain actuarially sound and the drastic reduction in beneficiary choice resulting from beneficiaries' inability to disenroll freely, CCHA is concerned about the institutional and geographic barriers to specialized care created by these county-based plans. When children have serious health problems, they need specialized care and treatment earlier than do adults. Thus, delays in referrals to specialists are both dangerous and costly with regard to children because their conditions tend to deteriorate faster than is the case for adults.

In our view, based on experience with the HPSM (discussed more fully below), one of two possibilities exists in connection with HIOs' relationship to children's hospitals:

(1) HIOs would not contract with childrens' hospitals and would refer to them only the most extreme cases that could not be handled by other providers within the plan; or

(2) alternatively, the HIOs would contract with children's hospitals, but at totally inadequate rates with no protections against increased acuity.

In addition, as regional tertiary care referral centers, each children's hospital in California treated patients from an average of 30 counties last year. Therefore, if single-county HIOs were to expand in number, the children's hospitals would incur the administrative costs associated with having to negotiate a substantial number of separate contracts with different county plans. Such a situation would present nothing short of an administrative nightmare. In a broader sense, proliferation of HIOs would also lead to significantly increased administrative costs for the Medi-Cal program through the creation of a whole new layer of bureaucracy in each county.

III. The Experience of Children's Hospital at Stanford

Many of these problems have in fact been witnessed at the Children's Hospital at Stanford ("Stanford Children's") in its brief experience with the HPSM in nearby San Mateo County. Despite substantial efforts to negotiate a contract, Stanford Children's does not currently have a contract with the HPSM for inpatient services, though it was able to negotiate a contract for its outpatient clinic. During these negotiations, the HPSM insisted on an inpatient reimbursement rate significantly below the hospital's Medi-Cal contract rate, which is already at a rate substantially lower than the hospital's costs. In the absence of a formal agreement for inpatient services, for the relatively few acute care cases that are sent to Stanford Children's, the Hospital has experienced an increase in acuity among these cases and has become all too familiar with "real life" examples of reduced access and quality of care for children enrolled in the HIO. In addition, Stanford Children's was forced to hire an additional billing clerk just for the HPSM patients because the forms and procedures are so cumbersome and because they differ from those for other Medi-Cal beneficiaries.

Clearly, though, the most disturbing aspect of Stanford Children's experience with HPSM has been repeated examples of institutional and geographic barriers to timely care for very sick children. The following is an all-too-frequent type of occurence: Felicia A. (we have changed her name in order to protect her privacy) is a fourteen-year-old Mexican-American child and an HPSM patient. Stanford Children's physicians have treated Felicia for a pulmonary condition over an extended period of time. Felicia was first seen in Stanford Children's Primary Care Clinic as an outpatient. On February 8, 1990, she was referred to the Pulmonary Clinic for evaluation of an abnormal chest x-ray and severe oxygen deficiency. After extensive testing, she was referred from the Pulmonary Clinic to Dr. C for a biopsy procedure.

Dr. C's office began the task of obtaining a Treatment Authorization Referral ("TAR"), which is required by Medi-Cal before doing this type of surgery. Dr. C's office phoned the Medi-Cal field office in San Jose and was told that the TAR had not been sent to the proper agency and that no action had been taken. At this point, Dr. C's office was informed for the first time that the child was covered by the HPSM, and the TAR form was forwarded to the HPSM office. While awaiting her biopsy, Felicia was seen in the Pulmonary Clinic on February 12, 15, 23, and March 2. By the time of her March 2 visit, her condition had deteriorated dramatically and the attending physicians determined that she needed to be hospitalized. Dr. P called to obtain phone authorization for hospitalization and scheduled surgery for March 5, 1990.

Dr. P's decision to admit Felicia was made at 10:30 AM on March 2. At 1:00 PM, an authorization for hospitalization from HPSM still had not been received. Once the admission was finally approved, no bed was available and her admission was delayed until the morning of March 3. A biopsy was performed on Monday, March 5, and Felicia developed respiratory failure following the procedure and had to placed on a ventilator. The results of the biopsy were inconclusive due to extensive tissue damage which, according to the attending physicians, was a result of the delay in performing the biopsy. It is likely that the biopsy would have resulted in a more conclusive diagnosis if it had been performed before her condition had deteriorated. Felicia remained in the hospital for more than a month, breathing with the aid of a ventilator. Her dependence on the machine eventually resulted in damage to her esophagus, requiring a tracheotomy. Fortunately, by April, Felicia was able to breathe again without the ventilator and was discharged.

This unfortunate case illustrates all too well the difference between pediatric medicine and general medicine. Children often have ongoing medical problems that can deteriorate rapidly, and early intervention and hospitalization are sometimes required to diagnose and adequately treat these conditions. With children, a disease or condition may not appear on the surface to be terribly severe, but more aggressive treatment is even more important. These considerations, however, are not recognized by the structure of the HPSM system. Nor are the problems discussed above limited to the HPSM. As reported by the National Health Law Program in its testimony at this hearing, there have been similarly disturbing patterns of delayed referrals and poor quality of care with regard to the SBHI.

IV. Proposed Solutions to Address Sick Children

Given these numerous concerns and issues, CCHA believes it would be inappropriate for Congress to approve an expanded number of county-based HIOs in California operating exempt from federal Medicaid requirements. Since last year, CCHA has explored a number of possible approaches to the present system of HIOs which would ensure enhanced access and quality of care for Medi-Cal beneficiaries, focusing in particular on children with special health care needs. In order to reduce the significant barriers to timely care for sick children, CCHA proposes a "system within the system" approach to address the needs of children with special needs. In brief, CCHA proposes that all inpatient hospitalizations for children who are jointly eligible for Medi-Cal and the California Children's Services ("CCS") programs be "carved out" from HIO payments and handled through the current Medi-Cal/CCS system of direct payment by the State, utilizing existing case management and claims processing capabilities. In addition, all HIOs in California would be required to contract with children's hospitals that historically have served the county in which the HIO is located, with payment at the state-wide negotiated Medi-Cal payment rates. This proposal would apply to all counties with HIOs in the state.

We believe that this basic approach would go a long way toward addressing problems regarding access to quality health services for this special population of children. The state of California is presently in the process of examining the impact of HIOs on CCS-eligible children within the state. The California Medical Assistance Commission ("CMAC") recently issued a draft report on the effects of including CCS-eligible conditions within the Santa Barbara and San Mateo plans. In view of the fact that this report is presently only in draft form, and may be subject to substantial revision, we would urge Congress not to move forward this year with any proposal to expand the number of HIOs in California. Rather, we would hope that Congress would see fit to await the completion of this CMAC report.

CCHA believes that the foregoing discussion, as well as the experience in other states with Medicaid managed care systems, underscores the need for more study of the impact of Medicaid managed care plans on Medicaid beneficiaries, especially sick children. Congress should not move forward with proposals to encourage Medicaid managed care until more extensive study has been undertaken. As reflected in our previous comments, we believe quite strongly that there is a need to examine the creation of a "system within the system" approach for all managed care plans which addresses the unique circumstances and services of children's hospitals and ensures access for the children who need special care. In this regard, we envision the creation of children's hospital-specific risk pools, as well as maintaining specialized case management and state-level payment mechanisms.

Conclusion

CCHA appreciates this opportunity to present its views on Medicaid managed care issues. As high-volume providers of Medicaid services and as advocates for access to quality care for all children, we look forward to the opportunity to work with Congress and the Administration on improving the Medicaid program. While the pressures of ever-rising health care costs will continue to be an issue, we must do all we can to ensure access and quality for our most vulnerable population -- our children.

5822h

STATEMENT OF STEVEN THOMPSON, DIRECTOR

ASSEMBLY OFFICE OF RESEARCH, CALIFORNIA LEGISLATURE

ON H.R. 2499

"THE MEDICAID LONG-TERM CARE DEMONSTRATION WAIVER ACT OF 1989"

On September 14, 1990, Congressman Roybal submitted a written statement to the Energy and Commerce Subcommittee on Health and the Environment. As one of the eight states who is developing a public/private insurance partnership and who would be authorized by H.R. 2499 to obtain a Medicaid waiver, I would like to respond to several of the issues raised by Congressman Roybal's statement.

Congressman Roybal indicates that the "current regulatory climate under which private long-term care insurance would be sold is simply not adequate to protect consumers against potentially abusive and deceptive marketing practices."

We feel this statement is not an accurate characterization of the regulatory climate in the eight states that would be participating in the Medicaid waiver demonstrations authorized by H.R. 2499. Each of the states who would be authorized to conduct demonstrations are very committed and active in seeing that adequate safeguards are in place to protect consumers who purchase long-term care insurance. The GAO report acknowledges the commitment each of the eight states have made to safeguard consumers interests: "each of the RWJF projects recognizes the need for strong regulation of long-term care insurance products offered under the projects."

The commitment of the RWJF states to consumer protection is well documented:

o All eight states that will participate in the Medicaid waiver demonstration have enacted legislation or regulation that exceed the National Association of Insurance Commissioner's model long-term care statute and regulations.

o The RWJF states have not only adopted the NAIC standards, they have played and continue to play critical roles in developing the standards. The insurance commissioners and staff from the departments of insurance of several of the RWJF states have played leadership roles in drawing up the existing standards which NAIC has adopted. These states are also involved in developing and proposing additional standards which are now under consideration by NAIC and are expected to be adopted at the next meeting in December. To make sure there is no repeat of problems which beset the Medicare Supplemental market, insurance commissioners in these states have become involved in the early stages of the development of the long-term care market. Active state participation in the development of long-term care insurance regulations has and will continue to shape the evolution of long-term care consumer-oriented insurance products.

o The insurance standards, consumer protection and design features which each of the eight demonstrations will require of insurers as a precondition for Medicaid certification will be superior to products currently on the market and will set the standards against which other long-term care insurance policies will be judged. This is as it should be. The purpose of the demonstrations is not to use Medicaid to encourage the indiscriminate purchase of long-term care insurance. Rather, the demonstrations seek to test the hypothesis that quality long-term care insurance products can protect consumers against the catastrophic costs of long term care while at the same time reducing impoverishment and public long-term care expenditures. I anticipate that demonstration projects will set the standards for the next generation of long-term care insurance products.

It would certainly be acceptable to us if the commitments of the eight states to consumer protection were incorporated in H.R. 2499 as the GAO report suggested: "a state should be required to demonstrate, prior to being granted a waiver, that its laws and regulations meet at least NAIC's minimum standards and that it has the capabilities to enforce the requirements. Further, because NAIC's standards continue to evolve as the market evolves, a state should be required to maintain its standards to at least NAIC's minimum levels."

Finally, Congressman Roybal's statement of September 14, 1990 noted that the GAO investigators were not able during their review of the eight state demonstration projects to physically examine even one policy that the federal government would be required to endorse.

The GAO was unable to examine actual policies because the demonstration states are not endorsing long-term care insurance products already on the insurers' shelves and currently being marketed, but are requiring insurers to develop new policies to meet the high standards the demonstration sites require as a condition of state certification. The finalization and production of new insurance policies to meet each state's standards cannot occur until the Congress passes the Medicaid wavier legislation permitting the demonstrations and specifies the conditions under which HCFA will be authorized to approve state waivers. It is reasonable to expect the insurers and states to develop the actual insurance policies and present them to the Congress and GAO before the Congress passes legislation authorizing the demonstration?

STATEMENT OF
AMY E. HIRSCH, ESQ.
AND
RICHARD P. WEISHAUPT, ESQ.
OF
COMMUNITY LEGAL SERVICES, INC.

On behalf of our clients, many of whom find lack of adequate health care of pressing concern, we welcome this opportunity to submit written remarks on the Administration's proposal to expand greatly the delivery of health care through capitated rate programs, such as Health Insuring Organizations (HIOs) or more traditional Health Maintenance Organizations (HMOs). We have read the Inspector General's report on Pennsylvania's HIO and the bidding controversy that has been engendered. Rather than comment at any length in that area, we would like these remarks to be seen as a supplement to the IG's report, so that the committee will have a sense of some of the other issues that have come to the fore in the years that Pennsylvania has had an HIO in operation. Despite a number of reports by various agencies, there has been little sophisticated and effective monitoring of the HealthPASS program at least in two critical areas: fiscal soundness and quality assurance. In both areas the performance of the HealthPASS provider has been seriously deficient and disaster has been only narrowly averted.

Fiscal Soundness

In the area of fiscal soundness, we now know the first HealthPASS provider, Penn Health, was on shaky ground, at least from the time that its parent company, HealthAmerica was acquired by Maxicare in 1986. Since the acquisition, Maxicare posted a loss in every quarter. Maxicare filed for bankruptcy in March

1989, its financial collapse having been precipitated by its overly aggressive acquisition of health care plans at vastly inflated prices. Since Maxicare was a publicly traded company, this over-extension should have been detectable by any diligent regulatory agency. Instead, waivers were sought and approved literally on the basis of attaching a copy of Maxicare's annual report to the waiver application. Despite this lack of documentation, the Health Care Financing Agency twice approved the waiver virtually without comment in this crucial area.

Maxicare's fiscal instabliity almost tore a gaping hole in the fragile fabric of Philadelphia's health care system. Payments to health care providers slowed to a trickle and then stopped altogether when Maxicare filed for bankruptcy. Several hospitals with HealthPASS contracts filed for bankruptcy at or around this time and although all of these institutions had long hovered near the edge of insolvency, certainly delayed payment from HealthPASS only exacerbated the situation. We do know that before DPW stepped in and made interim payments to the hospitals (essentially paying twice for the same services, since HealthPASS had already received money to provide this care) several more fiscally sound institutions were damaged. Newspaper reports from that period reveal that the finance director of the Mercy Catholic Medical Center, George Walmsley, said that his hospital was owed approximately $1.5 million and was in danger of running out of money. The prestigious Children's Hospital of Philadelphia (CHOP) was $3.3 million short. Another teaching hospital, Presbyterian Medical Center, was unpaid for $4 million worth of care. While no one has done any studies of the matter, it is safe to assume that such cash shortfalls must have had an adverse effect impact on patient care, whether it be an optional test that wasn't run, a nurse that wasn't hired, an innovative new program that got squelched or a pregnant woman who had to wait 3 extra weeks before she gets an appointment. Perhaps no one will ever "prove" these results, but our knowledge of the health care system in Philadelphia convinces us that they took place regularly as a result of the Maxicare bankruptcy.

For smaller providers, the results of the bankruptcy were even worse. While the hospital association had the political clout to obtain interim payments and many of its members had the financial resources to weather the storm in reasonably good fashion, smaller, community based providers were particularly hard hit. The few home health care agencies in the HealthPASS area virtually ceased seeing HealthPASS patients. Family planning clinics were without any income for more than 6 months. Community health centers were strapped and at its worst, for a brief period, many HealthPASS patients found that they could not get necessary and even life sustaining prescriptions filled. Fortunately, permanent, irreparable damage to the health care system was avoided but not through any built-in features of the HealthPASS program. Next time we may not be so lucky.

Moreover, Maxicare's bankruptcy has had an adverse fiscal impact on the state in that, as we have already described, the state agency was compelled to make additional payments to many providers to keep them afloat during the bankruptcy period. As a result, most, if not all, of the cost savings have been dissipated.

Quality Assurance

Another similar problem in monitoring has been the failure of HealthPASS to have functioning Quality Assurance mechanisms in place. Neither Penn Health nor its successor, HealthCare Management Alternatives (HMA) have lived up to their promise to have a fully operational Quality Assurance program in place at all times.

One would think that quality assurance would be one of the highest priorities of the HealthPASS provider and of the state agency. After all, the Medicaid statute permits such programs to restrict access to care only "if such restriction does not substantially impair access to such services of adequate quality where medically necessary." 42 U.S.C. §1396(b)(1). HCFA regulations further require states seeking such waivers to demonstrate the effect of the program on recipients regarding access to care and quality of services. 42 C.F.R. §431.55. The regulations also make it clear that restricting freedom of choice is only permitted when the state agency has standards in place to assure the quality of care is maintained. 42 C.F.R §431.55(f). To the contrary, our state agency has totally delegated the responsibility for devising standards to assure quality of care to the HealthPASS provider and has been lackadaisical in requiring the provider to adhere to the standards that it develops. With the knowledge and at least tacit permission of HCFA, the state agency has prevented the normal regulator of health care, the state Department of Health, from being involved in HealthPASS regulation or monitoring. Incredibly, for the first four years of HealthPASS operation no one in DPW with oversight responsibility had any background in health care or any professional degree in health care, medicine or public health. Despite this lack of experience in the field, and the abdication of the role developing standards, HCFA approved the waiver request.

The results were predictable. Penn Health never had a fully functional Quality Assurance program. This was reported on by HCFA in 1989.

> "The HIO activity reports do not reflect any hospital chart review activity until December 1986, eight months after the scheduled implementation date ... 270 hospital charts had been reviewed as of the end of January 1987, contrasted with the 462 charts which should have been reviewed according to the QAP [Quality Assurance Program]. We also found that the hospital chart review activity performed did not cover all of the required criteria. Rather, the focus was on medical necessity/utilization review..."

Furthermore,

> "The HIO deviated from the sampling plan ... to focus on sites with large enrollments or where problems were suspected and limited the number of

> enrollee charts to 10 regardless of panel size ... In practice, the HIO concentrated these reviews on medical charting practices. In the majority of cases, there was no evidence of physician evaluation of the quality of medical care being provided to enrollees."

Even DPW, once Penn Health had gone bankrupt, acknowledged as much in requesting waiver renewal. There, DPW acknowledged what advocates had suspected for some time, namely that problems called in to the hotline were not being reported to the QA Department.

Of course, once HMA took over, things were supposed to be different. They were not. The prestigious Joint Committee for the Accreditation of Health Organizations (JCAHO) reported that as late as March, 1990 HMA still did not have an operational Quality Assurance program:

> It was noted that the Quality Assurance Program is not comprehensive. Current activities do not adequately address the scope of care provided.

The JCAHO also reported confusion in the QAP and little or no activity in key areas, such as emergency care. DPW refuses to release the report.

Furthermore, a number of studies, although generally giving HealthPASS passing grades, have identified possible areas of deficient care. Instead of investigating these areas and adjusting QA programs to look at these areas, the state agency and the HealthPASS contractor refuse to acknowledge that there is any room for improvement. Such self congratulation is dangerous and irresponsible.

Drug and Alcohol Programs

One area of health care that has left all health care systems struggling is Drug and Alcohol programs. This is not an area where anyone can say with confidence that the needs of the Medicaid population are being adequately addressed. With this in mind, however, it should be noted that attempting to deliver such care through a capitated rate program has particular problems that must be addressed.

First, it must be remembered that such care is expensive and that patients in need of such are frequently difficult. This means that any provider placed at financial risk will have a strong incentive to avoid taking on such patients. We have seen evidence that primary care providers will actively seek to avoid such patients. Moreover, in areas where recipients have a choice of health care plans, plans have a strong incentive to market themselves in such a way as to avoid signing up such patients. There are no easy answers to this situation in part because drug involved patients are very expensive to treat. If a concentration of patients turns up in any one practice or plan it undermines the risk spreading principles upon which capitation is based. This, in turn, frustrates the obvious solution to require drug or alcohol involved recipients to be seen in one of a small number of practices.

Second, we have observed that HealthPASS, particularly under Penn Health, went to great lengths to restrict access to drug and alcohol services. Indeed, it got so bad that many people seeking treatment actually moved out of the HealthPASS area or give DPW false addresses. This still takes place. The Public Defender Association had to have several meetings with HealthPASS just to make sure that clients with court referrals for drug detox and treatment could obtain care.

Third, to the extent that mainstream health plans are utilized to deliver care, special attention must be taken to insure that these plans have actual referral mechanisms in place for the considerable number of substance abusers that are likely to need treatment. Many HMOs simply are not prepared to deal with the volume of patients needing drug related services, whether for their middle class or for their low income patients.

Finally, the goal of coordination of care is a difficult one to achieve. In HealthPASS, primary care physicians do not get drug and alcohol records of treatment, leading some to complain about the detrimental affect this can have on coordination of care. However, to allow physicians access to these records raises serious privacy concerns, since recovering people are very reluctant to have anyone know about their problems. Further, sharing such information with physicians can lead them to force such patients to leave their practice and find care elsewhere.

These are not easy problems to solve, however, not thinking about them simply because they are difficult, the approach taken by HealthPASS, has only made matters worse.

ACCESS TO CARE

One of the justifications for mandatory case managed care is a promise of increased access to care by guaranteeing each enrollee a primary care provider. In several critical areas HealthPASS has been unable to deliver on this promise, whether under PennHealth or HMA's management. As discussed below, there are very serious problems with access to primary care providers, especially pediatricians, access to specialists and access to prenatal care. These problems have resulted in confusion, denials of care, delays in obtaining care, lack of continuity of care, and poor health outcomes.

ACCESS TO PRIMARY CARE PROVIDERS

HealthPASS has not ensured sufficient and adequate access to primary care providers. This is particularly true in South Philadelphia, and particularly true as to pediatricians. In the southwestern half of South Philadelphia (19145 zip code area), there are only two sites at which HealthPASS participants can receive pediatric care. Both are at city-run health centers, rather than private physicians, and one of these is the city's Health Center #2. Such health centers and clinics generally do not assign participants to a particular doctor, but to the site itself, thus depriving participants of continuity of care. Similarly, in the northwestern part of South Philadelphia (zip code area 19146), there are only three sites which have pediatricians, and all of them are health centers rather than private physicians. (Indeed, there is only one HealthPASS private physician in zip code 19146 who does not practice in a health center or clinic setting.) The other areas of South Philadelphia (zip codes 19147 and 19148) follow this same pattern.

This paucity of pediatricians in particular leads to many problems. First, young HealthPASS participants are deprived of the option of visiting a pediatrician in other than a health clinic atmosphere, thus giving them fewer options than participants in the Medicaid fee for service system. Moreover, because the health center sites containing pediatricians are not located in close proximity to the homes of many HealthPASS participants, even the alternative of a health center pediatrician can mean a one and one-half hour public transportation trip.

For many children, the only alternative for obtaining primary health care for children is to choose a primary care provider whose main area of practice is in adult medicine. This once again amounts to disparate and reduced treatment alternatives for HealthPASS participants. It is also not good health care. Yet throughout the time that HealthPASS has been operating 5,000-10,000 young children have been followed by non-pediatricians. Children have special needs that are not the same as those of adults. Different protocols and medical knowledge are necessary and a much greater emphasis on preventive care is appropriate. Many physicians who primarily treat adults do not even have the equipment necessary to diagnose and examine young children. Despite this, HealthPASS has allowed a large number of children to be assigned to adult care PCPs. Moreover, the use of adult care PCPs only exacerbates the poor linkage between HealthPASS and the EPSDT program. Despite our previous objections and the concerns expressed by HCFA, DPW and HealthPASS have done little to coordination in the two programs.

The problem of access to primary care providers is not limited to pediatricians. All too many adults are assigned to health centers or clinics where care is impersonal and fragmented or to attending physicians at teaching hospitals who never see the patient, entrusting actual hands on care to rotating residents. As a result, recipients who have complicated cases or who need referrals often find it very difficult to get care. Even participants whose Medicaid cards list a specific doctor at a health center or hospital-based clinic are not assured of seeing that particular doctor when they visit the clinic. In fact, many clinics which act as primary care providers make no effort whatsoever to ensure that HealthPASS participants have continuity of care, which is not only an issue affecting the quality of care that a participant will receive, but also the entire concept behind the case management system. Much of the care at hospital based clinics is rendered by residents who have no training in their duties as PCPs and for whom there are no standards regulating practice.

ACCESS TO SPECIALISTS

HealthPASS participants have experienced difficulties obtaining referrals to medical specialists. This is due, in part, to misinformation on the part of primary care providers.

Many doctors, for example, have the false impression that certain hospital based specialty clinics will not accept HealthPASS. Thus, they do not even attempt to refer their patients to those facilities. As a result, primary care providers either forego referring patients entirely or they refer patients to a less appropriate site.

In particular, there seems to be a decided lack of information about the services covered by HealthPASS, and those services which can still be obtained on a fee for service basis. Some primary care providers are under the impression, for example, that a patient cannot receive outpatient psychiatric treatment unless they receive a referral from their primary care provider. Thus, they believe that HealthPASS patients can only receive outpatient psychiatric care from a mental health clinic which accepts HealthPASS. Again, this limits the options for a HealthPASS patient unnecessarily and results in both inappropriate treatment and lack of treatment. Part of the problem here is that DPW has never published regulations or guides for the program and both providers have not produced concise, clear cut guides for physicians to use. Moreover, the abrupt change from PennHealth to HMA and the resultant modification in practices has also added to the confusion.

HealthPASS patients are also receiving inappropriate referrals due to the paucity of specialists, who will accept HealthPASS. [1] Because there are so few cardiologists, gastroenterologists, surgeons, etc. who accept HealthPASS, primary care providers are making specialty referrals to internists who are not Board certified in an area of specialty, but who nonetheless holds themselves out as consultants in a specialty area. Moreover many HealthPASS patients can only receive specialty care if their PCP actively seeks out a specialist who will see them as a charity patient outside the HealthPASS system. This has been and continues to be especially true for orthopedists and anesthesiologists.

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[1] The lack of hospital-based specialists and inadequate documentation as to how necessary specialist services are supposedly being provided is discussed in the HCFA assessment.

Access to specialists is further limited by the procedure for obtaining such referrals. Many patients complain that they cannot receive a referral telephone consultation with their primary care provider. Rather, a written referral form must be obtained in person in all circumstances. This places an unnecessary barrier to obtaining needed treatment. A patient must go to her primary care provider's office during his office hours - which are, in all too many cases limited to no more than 20 hours per week - in order to get a signed referral form. In hospital based facilities, in particular, patients have complained that there is confusion over who has the authority to complete referral forms and which forms need to be completed. All too often, this results in unnecessary delay in receiving a referral.

ACCESS TO PRENATAL CARE/INFANT MORTALITY

Access to prenatal care and birth outcomes have apparently worsened since HealthPASS was initiated. For example, in the poorer areas of West Philadelphia (City Health District 4), which is completely contained within the HealthPASS area, 12% of women giving birth in 1984-86 had received inadequate prenatal care. In 1988 (the third year of HealthPASS' operation), 19.3% of women giving birth had received inadequate prenatal care. Similarly, in 1984-86, 13% of the infants born were of low birthweight; in 1988 that figure increased to 14.8%. The infant mortality rate for the District remained at 23.6/1,000 live births, a disgraceful figure. 2/ Prenatal care is a good test of how well HealthPASS is working. If properly managed care is being provided and access to care is being improved, or at least not worsened, then more women, not fewer, should be receiving adequate prenatal care. The percentage of low birth weight babies should be dropping, not increasing. HealthPASS has failed to address this crucial problem despite frequent promises to do so.

2/ All statistics are from the City of Philadelphia Department of Public Health.

WRITTEN TESTIMONY

Mr. Horace L. Sheffield, Jr.
Executive Director
Detroit Association of Black Organization

Mr. Chairman and distinguished members of the Subcommittee, my name is Horace L. Sheffield, Jr., and I am Executive Director of the Detroit Association of Black Organizations (DABO). I am most appreciative for this opportunity to submit testimony on behalf of DABO in respect to Senate Bill 2605, the Pharmaceutical Access and Prudent Purchasing Act of 1990, and other proposals which would have a direct impact on the Medicaid Drug Program.

DABO is a coalition of more than 190 neighborhood groups, community associations, city-wide agencies, and affiliates of national organizations. We are a moving force in Detroit as well as throughout Michigan. DABO, organized in 1979, is committed to equal opportunity for all citizens through comprehensive programs that meet our community's needs, including education, employment training, housing, and with respect to this pending legislation--health care. We, collectively and individually, have been in the forefront of championing these important concerns as well as effectively addressing these needs throughout Detroit.

U. S. Senate Bill 2605, as a budget-cutting measure, shamefully seeks to save money in the Medicaid Program at the expense of the elderly, the poor, the children and the disabled. It would mandate that pharmacists substitute the cheapest alternative drug when filling prescriptions for medicaid patients. The pharmacists is required to make a "diligent effort" to call the doctor about the change. If the doctor can't be reached then, as provided by S. 2605, the pharmacist is mandated to give the medicaid subscriber a "three-day-supply" of the cheapest alternative drug.

The "three-day-supply" provision would certainly force Medicaid Patients to return to a pharmacy in three days. This is so because even with a "diligent effort", there would be hundreds of thousands of cases where this pharmacist would not reach the doctor. This would present a real hardship since its estmated that only 10% of medicaid patients have their own transportation.

We are, therefore, strongly opposed to this bill. The harsh restrictions it places on Medicaid drug availability will surely result in second-class medicine for the elderly, the poor, the children and the disabled. While originally touted as a cost containment measure, S. 2605 could end up costing taxpayers more money through additional bureacracy to administer such a program, and the increased need for more expensive hospitalization or surgery when new and improved drugs are denied to Medicaid patients.

It merits noting that black Americans suffer from tremendous disparities in medical afflictions: hypertension; cardivascular disease; diabetes; sickle cell anemia; and others. What's more, black Americans also suffer tremendous disparities when it comes to health coverage and access to quality treatment. S. 2605 would clearly make these disparities even worse.

Any effort to change Medicaid drug programs should surely include these points: 1. Medicaid patients must be assured maximum availability of medically necessary drugs; 2. the elderly, the poor, the children and the disabled should not bear the burden of reducing Medicaid prescription drug costs; 3. medical necessity, not price should determine which drugs are covered by Medicaid; and 4. Medicaid recipients should be afforded the same availability of quality health care and medically necessary drugs as non-Medicaid patients. There should not be a double standard of health care for America's aged, sick and disabled--regardless of ability to pay.

From our perspective-one of a front-line, community based organization-the implementation of the provisions of Senator Pryor's bill could prove not only a bureaucratic nightmare, but one which poses grievous health risks for all Medicaid patients. The risks include: Cheap, inappropriate or inferior quality drugs which may threaten the very lives of the patients. Delays in access to medically required drugs, given that treatment is often received in emergency rooms and walk-in clinics,with no consistent family physician to monitor the patient.

For these reasons, as well as that of genuine fairness--please do not deny quality health care to those least able to obtain such care, our nation's poor, sick and disabled--through imposition of further prescription drug restrictions.

Thank you, Mr. Chairman.

Healthcare Management Alternatives, Inc.

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September 24, 1990

Hand Delivered

The Honorable Henry A. Waxman
Chairman
Subcommittee on Health and the Environment
Committee on Energy and Commerce
U.S. House of Representatives
2415 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of Healthcare Management Alternatives, Inc. (HMA), I commend the Subcommittee's efforts to explore ways in which managed health care can better serve the needs of Medicaid recipients across the country. As you know, HMA administers HealthPASS, a managed care program serving Medicaid recipients in South and West Philadelphia. Through innovative health promotion activities, HMA hopes to harness the enormous potential of managed care to make a long-lasting contribution to the health and well-being of some of Philadelphia's most vulnerable citizens.

HMA's successful operational experience with the HealthPASS program can bring a useful perspective to the various alternatives being considered by the Subcommittee, and we would like to take this opportunity to comment upon several of the issues raised during the September 14, 1990, hearing on Medicaid managed care. We would also like to clarify several of the statements made about the HealthPASS program during the course of the hearing.

ENHANCING MANAGED CARE PERFORMANCE

The witnesses testifying before the Subcommittee generally recognized the ability of managed care to address many of the problems that plague Medicaid recipients and the traditional Medicaid fee-for-service system. These witnesses, notably Ms. Janet Shikles of the General Accounting Office (GAO), also identified several factors that have inhibited some managed care plans from realizing their full potential in the Medicaid

HealthPASS ... *"Because Your Health Comes First."*

program, including problems resulting from (1) inappropriate financial incentives, and (2) inadequate quality assurance. As we explain below, HMA has undertaken steps to ensure that none of the problems identified by the GAO will occur in the HealthPASS program.

1. Financial Incentives

The capitated payment system under which managed care plans operate offers a tremendous opportunity for cost-savings, by preventing unnecessary or inappropriate utilization and encouraging the provision of care in the appropriate setting. This fact has long been accepted in the private sector, and accounts for the steadily increasing reliance on managed care by many commercial insurers.

Nonetheless, as witnesses for both the GAO and the National Health Law Program noted, unless quality of care is properly assured, a capitated system risks creating incentives to stint on needed medical care and services. HMA uses a variety of mechanisms to eliminate this risk from the HealthPASS program.

Payments to the HealthPASS network of primary care physicians (PCPs) strike a careful balance between financial and quality of care concerns. Some financial risk is essential, in order to encourage PCPs to be prudent purchasers of services and to select appropriate care settings. Financial considerations, however, must not be permitted to dictate the care prescribed for any given patient. For this reason, HealthPASS PCPs are not at risk for hospital services, and have only limited risk for most specialty services.

An aggressive quality assurance program, emphasizing provider credentialing and a comprehensive series of medical audits, is the primary means of assuring that the financial incentives work properly and that HealthPASS providers render appropriate care. HMA's quality assurance program, which is described in detail below, is reviewed and evaluated quarterly by a national accreditation body, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). It includes protocols to monitor both overutilization and underutilization of services.

Additionally, in the HealthPASS program quality of care monitoring is administratively separate and distinct from the review and monitoring of the cost-effectiveness of medical services. By separating the quality assurance and utilization review functions, HMA ensures that cost considerations do not inappropriately influence quality of, or access to, necessary care.

Finally, HMA has instituted a number of measures to enhance members' access to the HealthPASS service network. All of our primary care physicians are contractually obligated to be available, either personally or through an "on-call" system, on a 24-hour per day, 7-day per week basis. This requirement is strictly enforced. Compliance is monitored by placing after-hours calls to physicians, and penalties are assessed if three instances of unavailability are established. HMA has also introduced a 24-hour toll free telephone hotline for HealthPASS members and providers. The availability of round-the-clock assistance and medical service ensures access and enhances appropriate utilization.

2. Quality Assurance Safeguards

A coordinated and comprehensive quality assurance program is an essential component of any managed care plan. In fact, quality assurance is a distinct advantage of managed care over the traditional Medicaid fee-for-service system, since quality safeguards in the latter program are often nonexistent or haphazard at best.

The primary goal of HMA's quality assurance program is to ensure that HealthPASS members receive medical care that is comparable or superior to that received by the general population. HMA does not believe that service levels in the Medicaid fee-for-service system provide a useful benchmark, since in the HealthPASS service area, as in many inner city neighborhoods, the fee-for-service system depends largely on poor quality "Medicaid mills." HMA's mission is to improve the quality of medical care provided to HealthPASS members, not to perpetuate former patterns of poor service.

The major elements of HMA's quality assurance program include:

Case Management - ensuring that the PCP serves as the coordinator of care, that proper referrals to appropriate specialists and other providers are timely, and that PCPs are accessible and available.

Medical Record Auditing of PCPs, OB/GYNs and other key specialists - ensuring that objective data are available to evaluate the medical care provided to members.

Provider Credentialing - ensuring that all participating providers are technically competent, subscribe to the case management concept, have satisfactory facilities, are accessible/available 24 hours a day, and deliver quality health care.

Daily Concurrent Review of inpatient hospital stays and continuing care plans - ensuring that quality assurance issues are identified and investigated immediately.

Comparison of Practice Patterns with normative data - ensuring that any deviations from accepted norms of practice are promptly identified and investigated.

Mortality audits - auditing all hospital deaths and reviewing data quarterly to identify and monitor major causes of death in the population.

Medical Care Evaluations - performing specialized, focused studies and problem-oriented audits in order to identify patterns of health care, to promote improvement in the care of specific illnesses, and to investigate areas of concern.

Member Satisfaction - a key outcome measurement of member's perceptions of the quality of care delivered to them and their satisfaction with the managed care program.

Community Advisory Board - through regular meetings, ensures that HealthPASS programs, services and policies are responsive to the needs of the community.

A second objective of HMA's quality assurance program is to measure the impact over time of the services provided on the health status of HealthPASS members. This information is then used to develop health education and outreach programs designed to prevent or correct any problems identified. For example, based on the data gathered during its first year as the HealthPASS contractor, HMA has initiated the following programs:

Family Planning/Prenatal Care - Through the Family Planning Council for Southeastern Pennsylvania, HMA provides enhanced prenatal services by family planning staff at the time of a positive pregnancy test result. This early prenatal care provides the opportunity to change risk behaviors, as well as to establish an immediate and continual relationship with a maternity care provider.

Lay Home Visiting Program - With the Health Federation of Philadelphia, HMA has agreed to provide pre- and post-natal home visits to HealthPASS pregnant women using trained community residents under the supervision of a nurse. The program brings medical care, education and support to women early in pregnancy up through the child's first birthday.

School Based Health Clinic - HMA has agreed to fund the first middle school-based health program in Philadelphia. The project is a cooperative effort between HMA, the School District of Philadelphia and Spectrum Health Services, Inc., a non-profit community health agency. The program is intended to provide appropriate and sensitive preventive and therapeutic services to youngsters where they are -- in the schools.

Head Start Program - HMA is funding two new Head Start classrooms in Philadelphia, the first time a private corporation has been directly involved in facilitating the delivery of a Head Start program. Major components of the Head Start program are education, health, parent involvement and social services.

In addition, HMA has implemented a variety of health education measures. These include cancer education campaigns, focusing on smoking cessation and breast self examination; informational publications on a variety of health topics; member and provider newsletters; support groups for pregnant teens; and drug and alcohol prevention classes.

The education and outreach activities just described -- which are funded through HMA's administrative funds, and not out of the moneys earmarked for medical services -- demonstrate the benefits that managed care can bring to a Medicaid population. These important preventive health programs and services would simply not be available to the same extent, or perhaps at all, in the traditional Medicaid fee-for-service system.

Similarly, it is unlikely that programs such as these, which are specially targeted to the needs of the HealthPASS service community, would be available to Medicaid recipients enrolled in a managed care plan that served both Medicaid recipients and commercial members. Indeed, given the low income level and high rate of unemployment in the HealthPASS service area, most commercial managed care plans would be not be eager to market their services to persons living in these Philadelphia neighborhoods. If such plans did market to the HealthPASS community, it is extremely unlikely that they would be able to enroll commercial members in any significant numbers.

For this reason, HMA wholeheartedly supports a proposal made by Ms. Barbara Hill, President of the Johns Hopkins Health Plan, in her testimony before the Subcommittee. Appearing on behalf of the Group Health Association of America, Ms. Hill recommended relaxation of the so-called "75/25" composition of enrollment rule to permit all-Medicaid plans in medically underserved areas.

Under current law, Medicare and Medicaid beneficiaries may comprise no more than 75% of a plan's total enrollment. As Ms. Hill noted, however, in many communities with large numbers of Medicaid recipients it is simply not feasible for managed care entities to attract the necessary 25% commercial enrollment. Thus, the 75/25 rule, which was intended to ensure quality of care to Medicaid recipients, may actually have the effect of reducing these persons' access to quality care.

As the HealthPASS program demonstrates, it is possible to assure quality health care within the context of an all-Medicaid plan. Indeed, HealthPASS suggests that Medicaid-only plans present the opportunity to target services more effectively, thereby actually improving the quality of the care and services available to recipients. Additional flexibility in the composition of enrollment rule, provided adequate quality safeguards are present, could therefore enhance considerably managed care's contributions to the Medicaid program.

THE HEALTHPASS PROCUREMENT

At the September 14 hearing, Thomas D. Roslewicz, Deputy Inspector General for Audit Services of the Department of Health and Human Services, discussed his office's audit of the procurement process that resulted, in June 1989, in the selection of HMA to administer the HealthPASS program. While we are pleased that Mr. Roslewicz reported the auditors found no specific acts of wrongdoing in connection with the procurement, we are concerned that his testimony was misleading in several significant respects. We would like to take this opportunity to clarify the record for the Subcommittee.

1. No Federal Investigation is Pending

Deputy Inspector General Roslewicz implied, both in his prepared statement and in response to questions from the Subcommittee, that the Federal Bureau of Investigation (FBI) is investigating the award of the HealthPASS contract to HMA. This suggestion is apparently incorrect. To our knowledge, the FBI is not now investigating the HealthPASS procurement, nor was that agency ever involved in an investigation of the contract award to this company. The Office of Inspector General confirmed this fact shortly after the hearing in response to questions from the Philadelphia Inquirer. (A copy of the Inquirer's article on this subject is attached.)

2. The Agreement Reasonably Apportioned Risk

Deputy Inspector General Roslewicz also stated that HMA's first HealthPASS contract, had it run its full term, would have resulted in a "windfall" of 29.5 million dollars to this company. In the course of litigation between HMA and the Department of Health and Human Services, we took strong issue with this assertion; we believed then and still believe that careful examination of the contractual provisions at issue undermines any such assertion.

The auditors failed to appreciate that the agreement between HMA and Pennsylvania was the product of a negotiated procurement, and that flexibility in developing the terms of the contract was both contemplated and intended. HMA, based on data presented by the Commonwealth in its Request for Proposals (RFP), submitted a fixed-price bid equal to 91.5% of the estimated fee-for-service costs for persons enrolled in HealthPASS. Once selected as the lowest bidder, HMA and Pennsylvania negotiated specific contractual provisions that gave the Commonwealth the benefit of this bargain, but at the same time protected HMA from unanticipated costs. When viewed in its entirety, the agreement certainly could not be said to result in a windfall to HMA, since the company's total payments would not have exceeded the fixed price that it bid -- that is, 91.5% of the estimated fee-for-service costs.

Moreover, when examined in detail, the three specific provisions of the agreement which the auditors maintained would result in the payment of undeserved funds to HMA cannot fairly be said to confer any such unearned benefit. We discuss each of these provisions in turn below.

a. Minimum Enrollment for Purposes of the Administrative Fee: The agreement provided for two categories of payments to HMA: payments for medical services and payments for administrative expenses. HMA's administrative fee was calculated based on a minimum enrollment of 88,125 persons. The auditors believed that this enrollment "guarantee" would result in a windfall if enrollment declined below the minimum level. On the contrary, this provision was intended to hold HMA harmless for uncontrollable changes in HealthPASS enrollment -- a possibility which all parties agreed would affect payments, and a risk which was assumed by Pennsylvania in the HealthPASS RFP.

The RFP discussed the effect that unanticipated and unpredictable changes in either level or composition of enrollment might have on the contractor. Pennsylvania stated clearly in that provision of the RFP its intent to negotiate payment rates to avoid both uncompensated losses by, and undeserved windfalls to, the successful bidder. Consistent with this intent, the terms of the RFP were such that the risk of a decline in enrollment was assumed by Pennsylvania and not by the contractor. The enrollment guarantee -- which applied to administrative expenses only -- represented the Commonwealth's assumption of this risk.

b. Total Payments for Administrative Costs: The auditors estimated that total payments to HMA for administrative costs would be greater than payments for similar costs made to the previous HealthPASS contractor. They then concluded that this constituted yet another "windfall" to the company. The auditors failed to note, however, that HMA's payments for administrative costs were limited to 12.3% of total payments, whereas no comparable limit applied to the previous contractor's payments for administrative costs. Thus, administrative payments to HMA, when calculated as a percentage of total payments under the contract, would not have exceeded those made to the previous contractor. Moreover, HMA's total payments, when calculated as a percentage of fee-for-service costs, would have been less than those made to the previous contractor.

c. Payment of Interest Income: The auditors maintained, finally, that payment of interest income on program funds would result in a windfall to HMA. Once again, the auditors were mistaken. Payment of interest income is a standard term of a managed care risk contract. Indeed, the former HealthPASS contractor, with HCFA's approval, earned interest income. The HMA contract merely continued this practice, which was known to all bidders. Significantly, interest income would have been paid to HMA only if there were sufficient funds available to pay all valid outstanding medical claims, including incurred but not reported claims.

Thus, the alleged "windfall" to HMA was at bottom a reasonable apportionment of risk, arrived at through arms-length negotiations. The provisions at issue were entirely consistent with industry practice, as well as with the previous, HCFA-approved HealthPASS contract.

3. Reprocurement Resolved Controversy

Finally, Deputy Inspector General Roslewicz's testimony should be viewed in light of the events that have taken place since the release of the audit reports -- which, it must be emphasized, addressed only the procurement process, and not HMA's performance in administering the program -- in July and October 1989. Both Pennsylvania and HMA disputed the audit findings, and litigation ensued over the decision of the Health Care Financing Administration (HCFA) to accept the audit findings and disapprove Pennsylvania's contract with HMA. Significantly, HCFA chose not to defend its decision, opting instead to work toward a settlement of the dispute. The Court played an active and positive role in facilitating such settlement so that HealthPASS members would suffer no lapse of managed care.

Settlement was accomplished in May 1990, with the full participation of HCFA, Pennsylvania, HMA, and HealthPASS providers and recipients.[*] Under this compromise, HCFA agreed to approve an abbreviated contract to HMA, and Pennsylvania agreed to conduct a new procurement for the HealthPASS contractor. This solicitation attracted four bidders, and the contract was once again awarded to HMA. As Deputy Inspector General Roslewicz acknowledged in his written statement, the HCFA official who participated in the selection commended the Commonwealth for its adherence to state procurement procedures.

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[*] The Pennsylvania Health Law Project intervened in the litigation on behalf of HealthPASS members, and strongly supported continuation of the HealthPASS program.

Thus, the HealthPASS procurement "controversy" appears to have been resolved to the satisfaction of all of those most concerned with the program -- HCFA, Pennsylvania, HMA and, most importantly, HealthPASS providers and recipients.

* * *

HMA, through its involvement in the HealthPASS program, has begun to bring about real change in the lives of HealthPASS members. We would welcome the opportunity to work with the Subcommittee as it develops proposals to realize fully the potential of managed care for Medicaid recipients. I will contact Mr. Andy Schneider of your staff soon to discuss ways in which HMA can contribute to the Subcommittee's efforts.

Sincerely,

Anthony Welters

Anthony Welters
Chairman of the Board

Enclosures

cc: The Honorable John Dingell
The Honorable Norman Lent
The Honorable Edward R. Madigan
The Honorable Jim Bates
The Honorable Michael Bilirakis
The Honorable Thomas J. Bliley, Jr.
The Honorable Terry L. Bruce
The Honorable Cardiss Collins
The Honorable William E. Dannemeyer
The Honorable Dennis E. Eckart
The Honorable Jack Fields
The Honorable Ralph M. Hall
The Honorable Howard C. Nielson
The Honorable Bill Richardson
The Honorable J. Roy Rowland
The Honorable James H. Scheuer
The Honorable Gerry Sikorski
The Honorable Mike Synar
The Honorable Thomas J. Tauke
The Honorable Edolphus Towns
The Honorable Bob Whittaker
The Honorable Ron Wyden

Saturday, Sept. 15, 1990 The Philadelphia Inquirer 3-B

Federal probe of HealthPass contract ends

By Walter F. Roche Jr.
Inquirer Staff Writer

A federal probe of the state's handling of a multimillion-dollar contract for the HealthPass program in 1989 has been officially closed, according to an agency that first raised questions about the contract.

Judy Holz, spokeswoman for the Inspector General's Office in the U.S. Department of Health and Human Services (HHS), yesterday said the agency had forwarded information on the contract to the U.S. Attorney's Office, which decided that there was insufficient evidence to pursue the case.

"The case is closed," she said.

Holz's comments came several hours after some members of a congressional subcommittee had been left with the impression that the HealthPass probe was ongoing. The prepaid health-care program provides medical care to 82,000 low- income residents of South and West Philadelphia.

The contract in question is with Healthcare Management Alternatives (HMA), the firm chosen by state Welfare Secretary John F. White Jr. in April 1989 to run the HealthPass program. Though HMA took over HealthPass on July 1, 1989, the original contract, valued at more than $600 million, drew immediate criticism from the HHS inspector general.

Thomas Roslewicz, deputy inspector general for audit services in HHS, summarized two critical reports yesterday. According to the reports, the inspector general said state officials had failed to follow proper procedures in reviewing bids for the contract; had "not acted prudently or wisely" in negotiating the contract, and acted so that "reasonable people could conclude favoritism was involved." He noted that HMA was originally rated last of the five finalists for the contract.

Testifying before the House Subcommittee on the health and environment, Roslewicz said the two critical reports on the 1989 state contract award had been "forwarded to the FBI for review."

In response to questions from a committee member, Roslewicz said that he was not aware of the current status of that FBI review, but that an investigative unit within the Inspector General's Office was working with the FBI on the matter.

Asked why the reports had been forwarded to the FBI, Roslewicz said it was done because of the size of the contract and "the appearance that the state may have shown favoritism" to the winning firm.

Holz later said that the FBI had never actually become involved in the investigation, but that the information gathered by the inspector general's staff had been forwarded directly to the U.S. Attorney's Office.

And state officials said there never had been an investigation.

"There was no investigation and there is no investigation," said Vicki Smink, spokeswoman for the Department of Public Welfare.

Sam Turner, an attorney representing the firm that won the controversial contract, said he was not aware of any ongoing investigation by the FBI. Turner attended the hearing yesterday before the subcommittee.

As Roslewicz testified, the original contract was substantially revised after the two critical reports and a lengthy court fight between the state, HMA and HHS. Under the revision, the term of the contract was cut from 56 to 18 months.

Roslewicz also reported that HMA had already been selected for another contract to continue running HealthPass in 1991. He said the state selection process had been monitored by officials in the regional HHS office and they were satisfied that, this time, the state had followed proper procedures.

"We did not monitor the process," he said.

STATEMENT OF HEALTH INSURANCE ASSOCIATION OF AMERICA

EXECUTIVE SUMMARY

HIAA POSITION

For several years, the Health Insurance Association of America (HIAA), has firmly supported the concept of cooperative public-private long-term care financing arrangements on an experimental basis. HIAA believes that the current "system" is flawed but that workable solutions are complicated and call for innovation, experimentation and evaluation -- not a rush to judgement. The demonstrations proposed in H.R. 2499 will enable both the public and private sectors to test and identify the most effective answers to this most pressing and difficult national problem.

OVERVIEW OF THE RWJ DEMONSTRATIONS

The Robert Wood Johnson Foundation has funded eight state demonstration projects (CA, CT, IN, MA, NJ, NY, OR, WI) to test the use of insurance principles to fund long-term care. Using the existing Medicaid program as a foundation from which to work toward sound insurance goals buttressed by the private market, each demonstration project would create a public/private partnership to fund nursing home care and a variety of community based long-term care services. Under these plans, which vary slightly from state to state, individuals are offered an incentive of guaranteed protection of assets to purchase private insurance for long-term care. Typically, an individual participating in a plan would first receive nursing home or home care benefits from their private insurance policy. When that coverage runs out, they could apply for medicaid and protect one dollar of assets for every dollar their private policy has paid out in state approved benefits. The state plans designed around the RWJ projects also emphasize public education on the purchase of long-term care protection, increase consumer protection through regulatory oversight, and foster the development by insurers of a variety of private policies to cover a market over all income groups.

STATES ARE BETTER SUITED

States have been the locus for innovation in long-term care for a number of years. State government is the only entity with any substantial experience with the administration and financing of long-term care programs, and is also responsible for the regulation of insurance. These demonstrations will allow states to gather valuable service delivery system utilization and cost data which is the essential first step toward creating a more rational method for financing long-term care.

DEMONSTRATIONS MUST BE BUDGET NEUTRAL

The programs under H.R. 2499 will not increase state or federal expenditures under Medicaid. The design of the proposed demonstrations, as well as the enabling federal legislation, are by definition at least budget neutral. The participating state governments are not in the fiscal position to undertake new expenditures. Simulation estimates project that states can achieve break even budget results, and in some cases, savings. If savings can be achieved, there will be additional resources available for the Medicaid program.

WEALTHY INDIVIDUALS WILL NOT BENEFIT FROM MEDICAID

All of the states under H.R. 2499 are interested in the greatest level of participation possible. Of particular interest is the group most likely to spend down their income and assets to Medicaid eligibility levels. As is currently the case, some elders have resources too low to afford insurance. This group is better off continuing to rely on the existing Medicaid system. By reducing middle-class dependence on Medicaid, there should be more funds available for those with low incomes.

Wealthy people will not receive publicly-funded long-term care under the demonstrations proposed in H.R. 2499. In contrast, if a national social insurance program were enacted wealthy people would be eligible to receive long-term care. Given our current domestic and international economic situation the latter is not likely.

FEDERAL STANDARDS UNNECESSARY/BENEFITS MUST BE MEANINGFUL

Comprehensive federal standards that override state standards are unnecessary. Eight of the nine states have regulations in place governing the design and sale of long-term care insurance and regulations are pending in the ninth state (NY). In addition, major consumer education efforts, which will assure that people understand the benefits and limits of their policies, are also part of the demonstrations.

September 14, 1990

Health Insurance Association of America

The Health Insurance Association of America is the principal trade association of the commercial health insurance industry. The 330 HIAA member companies underwrite over 85 percent of the private health insurance available from commercial companies in this country. We appreciate the opportunity to discuss our role in financing the nation's long-term care bill and particularly the importance of legislation such as H.R. 2499.

- While the current "system" is flawed, the financing of long-term care is complicated and requires a thoughtful solution, not a rush to judgement.
- Fiscal realities and other national priorities make it irresponsible to place the financing burden primarily on either the nation's taxpayers or the federal government. All elements of society -- individuals, families, volunteer organizations, employers, and insurers must also play a vital role.
- There is a growing and critical role for private insurance to provide a better means of financing long-term care for those who can afford to protect themselves.
- There is a continued and indeed, greatly improved role, the government can play in financing long-term care for those without adequate resources to protect themselves.
- There continues to be a critical government role, independent of financing care, in data collection and research to further our collective knowledge about who needs long-term care, what services should be provided, and what the total costs to society will be.

The HIAA firmly believes that cooperative public-private financing and delivery arrangements should be promoted on an experimental basis. A comprehensive national policy should be based on a full understanding of the alternatives and their cost-effectiveness. Research and demonstrations efforts such as the

Robert Wood Johnson planning grants to the states to develop public-private financing and delivery models for long-term care are a very positive first step toward accomplishing these objectives.

Background

While there is increasing public awareness that long-term care is not a benefit of Medicare nor of Medicare supplemental insurance policies, the many facets of paying for prolonged health and custodial services in later years have yet to be solved. The statistics speak loud and clear:

- the lifetime risk of entering a nursing home is at around 40 percent; it is almost 50% for women.
- When an elderly person spends more than $2,000 per year out-of-pocket on health care, 80 percent of that is likely to go to nursing home care.
- New estimates peg the yearly cost of nursing home care at an average of $37,000.
- About 9 million people will require long-term care by the turn of the century. Currently about 70 percent of them receive care in their homes and communities from family members and friends. Another 30 percent need some type of paid assistance, and at one time or another 40 percent of all elderly will spend time in a nursing home.
- Providing long-term care is more than a matter of financing it. Long-term care delivery systems are mostly uncoordinated. In many cases where a nursing home placement is not desireable, it is often the only choice when other forms of long-term care assistance such as home health aides, adult day care, respite help simply do not exist.

New Developments in Long-Term Care Insurance

A national survey conducted last year by the University of Maryland's Center on Aging found surprising willingness by the public to purchase a long-term care plan if it met their long-term nursing home and home health care needs. Overall, over one-half of those surveyed indicated they would pay $100 a month for such a plan. In addition, two-thirds of full-time workers said they would be more willing to purchase a policy if it were offered by their employer, even if the employee paid all or some of the premium.

The long-term care insurance market is developing rapidly, as evidenced by the number of companies developing products, the number of individuals covered and the variety of products being developed. There are now well over 100 companies selling a long-term care product and almost all of this growth is since 1985. Today, about 1.5 million persons have purchased a long-term care plan.

More importantly, the products themselves are changing. The earlier products tended to be more limited. For instance, they covered only stays in a nursing home and then only following a hospital stay. But virtually all the newer products offer coverage of nursing home and home health care, without institutional gatekeeping mechanisms like prior hospitalizations. Instead, benefits are often triggered based on the need for assistance in personal care functions such as bathing, walking, and dressing. In addition, they provide inflation protection against future long-term care costs. We will see a continued trend toward more comprehensive and liberal benefit provisions as the market place becomes more competitive.

The recent introduction of employer-sponsored plans is particularly promising. These employee pay-all plans offer the opportunity to reach a large number of people efficiently during their working years when premiums are more affordable. Coverage in the workplace offers the additional advantage of employers selecting the best plan at the best price for their employees.

Today a total of 118 employers are offering long-term care insurance. In 1989, HIAA conducted a survey of the employer market and found that of the 57 plans with enrollment experience, a total o almost one half million employees had been offered a long-term care insurance plan. Most of the plans also allowed employees' spouses, parents and parents-in-law, as well as retirees and their spouses to obtain coverage. The average age of active employees electing coverage is 43 years.

Appropriate Public Financing Role

An estimated $56 billion was spent on all long-term care services in 1987. Over half, $30.6 billion, was paid by the public sector. Assuming no change in our current financing system, the Congressional Budget Office has estimated that this figure could increase between 50 and 200 percent by the year 2000.

Given today's fiscal realities and competing national priorities, we cannot expect the public sector to take on such an enormous and unwieldy financial responsibility. Instead, HIAA believes that public policy should be targeted toward finding ways to more effectively use the private resources already being spent for this care, thereby reducing future public long term care expenditures. Those who can afford to protect themselves should be encouraged to do so.

It is not the role of government to protect and preserve assets or income levels of individual citizens against the various contingencies of life. In general, it is the responsibility of individuals to plan for their own needs to the maximum extent possible. It is the role of government to provide sensitive and responsive support to those who face needs beyond their individual financial capacity to deal with them.

The government should target its limited resources to assist those who can least afford such protection. Private insurance products are not designed for, nor do they lend themselves, as financing vehicles for people who are already quite old, disabled, or poor. Providing care for this population should be the objective of the public sector, and reforms are needed to improve the government's ability to act as a responsible safety net for those who must rely on it.

Educating the Public

The need for better consumer education is the responsibility of both the private and public sectors. It is virtually impossible to sell a product to someone who already believes they have it. However, this is where we find ourselves with long-term care insurance. Education should begin early, so that working age people can plan for their potential long-term care needs while they have the income to do so.

State Regulatory Environment

Long-term care insurance is a new product that continues to evolve. Insurers need a state regulatory environment which is sufficiently flexible to allow for the development of new and different products but is equally effective in protecting consumers. In December 1986, the National Association of Insurance Commissioners (NAIC) adopted the Long-Term Care Insurance Model Act, with a Model Long-Term Care Insurance Model Regulation also adopted shortly thereafter. These models were drafted to establish standards for the design of long-term care insurance policies. Since that time, both the Act and Regulation have been amended a number of times to keep pace with the rapidly changing market and to ensure consumer protection in the long-term care insurance market.

The most recent amendments to the models address such issues as requirements for an inflation protection feature as an option in the policy and requirements that a standard outline of coverage be provided at the point of solicitation. Additional features include a 30-day free look period, and a prohibition of the use of a prior hospital stay before a policyholder becomes eligible for nursing home benefits.

To date 41 states have either passed the Model Act or a statute more stringent than the Model and 20 states have adopted the

Model Regulation. HIAA supports the provisions of these models and have made adoption in all states a top priority.

Summary and Conclusion

The flexibility of private insurance offers families and the elderly the preferred approach to prefunding long-term care for many Americans. And, over time, we believe private insurance will give millions of people an opportunity to be financially independent throughout their retirement years.

HIAA believes it would be a mistake to minimize the role of private insurance in designing a comprehensive national policy for long-term care. Instead, the public and private sectors must combine their efforts and knowledge to create a solution that will benefit most Americans today and in the future. This investment will pay off many times over as you and I grow older and it will help us avoid placing an insupportable tax burden on our children.

Thank you for the opportunity to provide our comments and we look forward to working with you to provide further assistance in this area.

STATEMENT

OF

RICHARD D. GODOWN,

PRESIDENT,

INDUSTRIAL BIOTECHNOLOGY ASSOCIATION,

This statement is submitted on behalf of the Industrial Biotechnology Association (IBA) to express our opposition to The Pharmaceutical Access and Prudent Purchasing Act of 1990 (S. 2605). IBA is a trade association representing more than 100 large and small biotechnology companies engaged in the research and development of new health care, agricultural, and consumer products. We believe that S. 2605 has major public health deficiencies and would stifle innovation by the developing biotechnology industry. We also believe it could lead to Japanese domination of the Medicaid market.

Essentially, if this bill was enacted, the Medicaid drug program would operate on a low-bid system. Bidding would take place among so-called therapeutic alternatives identified by a special formulary committee. The bidding would result in identifying a single drug as the drug of choice for each therapeutic category. Pharmacists would be required to dispense the lowest cost drug in the therapeutic class, regardless of whether that drug was specified by the physician, unless the physician takes extra steps to ensure that the requested product is the one actually dispensed. Companies whose products are excluded as a result of the bidding would suffer a loss of the entire Medicaid market in a particular region. The impact could be disastrous on a small company with only one or two approved products to sell.

Furthermore, the biotechnology industry is very concerned that enactment of S. 2605 could lead to Japanese dumping of biotechnology products on the Medicaid market. It is no secret that Japan has identified biotechnology as a technology in which they want to replace the U.S. as the world leader. Japan came to a similar decision about semiconductor chips shortly before they began dumping their chips on the U.S. market, at prices below their production costs, for the purpose of establishing U.S. market dominance. We fear that Japan's success in using unfair trade practices to destroy the U.S. semiconductor industry could be duplicated in biotechnology if price is the sole criterion by which products are selected for the Medicaid market.

IBA member companies are using techniques such as recombinant DNA and hybridoma technology to develop nearly 100 new "biopharmaceuticals," proteins that restore or augment the body's natural disease-fighting mechanisms. Many of these drugs are directed at serious, and often intractable, diseases such as cancer, AIDS, and arthritis, for which existing therapies are either nonexistent or inadequate. The 1990s promise an acceleration of advances in drug therapy because of biotechnology.

Most of the first wave of biotechnology products have been "breakthrough" therapies. However, once a breakthrough therapy is developed, a company will look for ways to incrementally improve the product so that a "second generation" version with superior characteristics (such as better patient response, ease of administration, and decreased side effects) can be offered. Historically, most new drug development has consisted of such trends. These improved products, which have been mischaracterized as "me-too" drugs, offer genuine therapeutic alternatives as well as the opportunity for marketplace competition in pricing. By treating such drugs as interchangeable, S. 2605 ignores the dynamics of the drug development process.

Companies will often embark on research on a drug that at the onset has the potential for being breakthrough therapy. However, since the development process for drugs takes seven to ten years, by the time the once-promising drug has actually reached the market, other treatment alternatives may already be available. The race to find a cure for AIDS is a prime example. Many biotechnology companies are spending tens of millions of dollars in an effort to find the solution for this deadly disease yet no one knows what alternatives may already be on the market by the time any given product is finally approved. S. 2605 in essence punishes companies for not having a crystal ball to foresee the therapeutic future a decade later.

Similar races are going on in other therapeutic categories. For example, there is currently no drug on the market capable of stimulating the production of white blood cells. Such a product, if ever developed, would have tremendous implications for a whole host of diseases. Currently, six biotechnology companies are trying to develop white blood cell stimulators. Every one of them can be legitimately regarded as a pioneering company undertaking high risk, but important, research and development. Five years from now, there will probably be several white blood cell stimulators on the market. But if S. 2605 is enacted, all of these products would probably be placed in the same therapeutic class, even though they might have slightly different patient profiles.

S. 2605 is detrimental to the development of breakthrough drugs in another way. High risk treatment for very serious diseases with which the scientific and medical communities have had little experience may require careful patient monitoring during the course of therapy. This is essential not only to ensure patient welfare but to protect manufacturers from liability associated with misuse of the product. S. 2605 contains provisions on compulsory licensing which would force manufacturers to relinquish patient monitoring through a controlled distribution and testing system or else lose their rights to the product.

While our concerns are shared with the traditional pharmaceutical industry, they are felt even more acutely by young biopharmaceutical companies. A biotechnology company's survival depends on the company's ability to obtain adequate revenues from its first few products. Many young companies rely on the revenues from a single product to pay back lenders and provide an adequate return to investors, while also financing next year's research.

Many of our member companies reinvest 40% or more of their revenues (not profits) into new drug development. Most of these companies have yet to turn a profit. Since these young biotechnology companies have discovered many promising new drugs, the quality of health care is likely to suffer if low bids and restrictive formularies are used to bar products from the Medicaid program solely on the basis of their cost.

TESTIMONY
HON. DAVID P. RICHARDSON, JR. PRESIDENT, NATIONAL BLACK CAUCUS OF STATE LEGISLATORS
AND
HON. LARRY YOUNG CHAIRMAN, HEALTH COMMITTEE, NATIONAL BLACK CAUCUS OF STATE LEGISLATORS

As president of the National Black Caucus of State Legislators, I am pleased to submit testimony for the Record of hearing held by the Senate Finance Committee Subcommittee on Health for the Family and the Uninsured regarding Senate Bill 2605, an FY90-91 budget proposal by the Office of Management and Budget, and possible alternatives to both measures--all pertaining to the Medicaid prescription drug program.

I am also chairman of the House Health and Welfare Committee in the Pennsylvania House of Representatives. Serving in these positions affords me a special view of Medicaid issues and especially those affected most--some of our nation's poorest and sickest citizens.

National Black Caucus of State Legislators members have long been involved in Medicaid issues. NBCSL itself has long-standing commitment to quality health care for all citizens, regardless of ability to pay. With this in mind the NBCSL, December 1989, adopted a Resolution calling for Open Formulary Legislation, providing Medicaid recipients unrestricted access to all drugs approved by the Food and Drug Administration. The organization's concern was again raised with the adoption of another Resolution on April 30, 1990 opposing any Federal proposal which would create barriers limiting a physician's right to choose the best medicine for his or her patients, and would prevent the establishment of comprehensive and open Medicaid prescription drug programs.

The future of Medicaid prescription drug benefits for America's 23 million Medicaid patients is at a crossroads. Major policy changes are being considered both in the bill for this committee and in the House. Similar changes are being considered by the Executive Branch as part of their effort to come to grips with an acceptable Federal Budget. This action will have profound consequences for this country's poorest and sickest citizens.

Medicaid patients are not like gun owners, environmentalists or special interests that are sufficiently well-organized to handle their own political battles. Therefore, organizations like NBCSL must enter the dialogue now and as forcefully as we can. We have a moral obligation to act on behalf of America's poor; those for whom, generally, Medicaid does not come close to meeting their health needs. Black citizens are particularly susceptible to a variety of conditions including hypertension, diabetes, cardiovascular disease, and sickle cell anemia which require the best available medication options.

Within the area of prescription drugs, most states have a tradition of offering *comprehensive drug coverage. This has assured that Medicaid patients have access to the medicines they need for a full range of health problems that afflict them. Some states, however, have experimented with restricting patient access to prescription drugs as Medicaid cost containment strategies. The consequences for the Medicaid patient have been disastrous. Ironically, the economic evidence strongly suggests that such restrictions have actually cost money, rather than saved money, as a result of the additional hospital and emergency services required when patients are not properly treated in the first place.*

In recent years, we have seen states learn from their experience and reverse access restrictions. Louisiana, South Carolina, Tennessee and Oklahoma are all recent examples of states which have removed restrictions and opened Medicaid patient access to needed prescription drugs. No longer are patients needlessly hospitalized or provided other, far more expensive services that become necessary when they are denied the most effective and appropriate prescription drugs. Their pain and suffering has been eased. Taxpayer dollars are being spent more efficiently.

The recent trend in the states has been encouraging. However, we are gravely concerned about Medicaid drug program changes currently under consideration. Earlier this year, we were presented with Senator David Pryor's Medicaid Drug bill.

Senator Pryor can be very proud of his accomplishments as a public servant. Those of us opposing his bill have the greatest respect for him. Nevertheless, the bill (S.2605) he has introduced, the one under consideration by this committee, remains of concern to the hundreds of national organizations and leaders who care about the health needs of the poor. Senator Pryor's proposed legislation was presented as a bill that would expand access to critical prescription drugs. Those of us who have examined the fine print, however, see tremendous problems the bill would create for the Medicaid patient: 1) a national list of drugs stamped acceptable for Medicaid patients; and 2) pharmacist to call the doctor to talk him into substituting a cheaper drug said to have "similar" effects.

Despite the outpouring of protest, the Senator's staff has consistently maintained that the access restrictions, so clearly seen by so many of the nation's most important interest groups and leaders, are not really there or are not serious. They are wrong.

What is worse, the Office of Management and Budget seemingly pulled an early draft of the Pryor bill out of the waste paper basket and put it on the table for consideration as part of the Budget Summit negotiations. OMB proposed to save money by having the pharmacist automatically switch Medicaid prescriptions to the cheapest drug in a given class without even telling the physician. This is not only bad public policy, but outright deadly for the Medicaid patient. Therapeutic substitution-overt or covert-is unacceptable!

It is up to those organizations who speak for the poor, the sick and disabled to join together to make sure that a small group of elite, stall-level policy technocrats do not impose some needless nonsense that, in their effort to gouge the drug companies; 1) rams second-class *medicine down the throats of America's Medicaid patient; 2) makes fools of our country's physicians by intruding on their valued practice of modern medicine, for which they are so extensively educated; 3) ends up costing taxpayers money to run a still larger health care bureaucracy; and 4) puts people in the hospital when they are denied appropriate drug treatment.*

Of course, we all want to spend our underfunded Medicaid program dollars wisely. But trying to reduce prescription drug costs will probably backfire by increasing overall Medicaid cost--causing extensive, needless pain and suffering in the process. Prescription drugs account for only 6.7 percent of total Medicaid spending. This fact alone would indicate that obtaining meaningful savings from this program component will be difficult, if not impossible. Further, "brand-name" or "single source" drugs account for only about a third of Medicaid drug expenditures--with the other two-thirds going to pharmacist fees and margins and generic drugs. The seeming zeal to single out the brand name fraction of the Medicaid drug budget for savings caused added concern since these drugs tend to be the newer, more effective and preferred treatments.

Inordinate focus on curbing the amount of money spent on this segment of the Medicaid drug budget will inevitably increase access problems for the Medicaid population when it comes to these special products of our country's massive government and industry investment in biomedical research. Policies that steer patients and physicians away from these newer and more effective medications are counterproductive both in terms of quality health care and pure economic efficiency. As in the states, such policies are likely to hurt the millions of children, blind, older Americans, and others who depend so greatly upon the Medicaid program.

It really scares me to know that so many Hill staffers are now looking to California's Medicaid officials for guidance as to how a "Pryor II" bill should look and how drugs should be provided to the poor in our other 49 states. California's Medi-Cal drug program is the shame of the great State of California. Medi-Cal bureaucrats pride themselves on the fact that they have created one of the most restrictive Medicaid drug programs in the nation.

Many of the most important new prescription drugs approved by the U.S. Food and Drug Administration during the 1970s and 1980s have been systematically denied Medi-Cal patients through its highly restrictive formulary and "Treatment Authorization Request" process designed to discourage California physicians from prescribing the most appropriate drugs for their Medicaid patients. By the end of the last decade, Medi-Cal officials were dragging their feet an average of 54 months after approval by the FDA before it would add a new drug to its restrictive list of medications deemed appropriate for Medi-Cal patients.

The crocodile tears shed over the years by Medi-Cal officials as they point the finger at various health care providers fool no one. Poor Medi-Cal patients have been denied health care commensurate with that of the larger society. Medi-Cal officials have never been sensitive to the devastating impact of many of their own Medi-Cal patients nor have they had a handle on the economics of their own program. Medi-Cal officials have never saved California taxpayers *a dime through their cynical and restrictive prescription drug policies. Medi-Cal officials are not the friend of Medicaid patients and have no credibility on this issue whatsoever.*

We do not want a Medi-Cal type drug program in Pennsylvania, in Michigan, in Texas, in New York, in Georgia, in Maryland, or anywhere else! We intend sending a message--loud and clear--on this subject to all Senators, House members, Secretary Sullivan, and the White House: First, you don't cut critical safety net programs--including Medicaid and its essential prescription drug component--as the nation heads into a recession. Second, ill-advised schemes to contain drug costs should be removed from consideration.

With the pharmaceutical companies now coming to the table with legislative proposals on this matter--and actually entering into contracts to provide discounts to the states for their drugs reimbursed through Medicaid--Congress and the Administration should leave well enough alone. Press reports indicate that many of the nation's largest pharmaceutical companies--whose drugs account for more than half the Medicaid market--are now negotiating such deals.

We encourage this committee and others to look for ways to improve Medicaid prescription drug benefits. We ask your help in finding ways to roll back existing restrictive formularies and prior approval systems that deny access in the states where such restrictions have become particularly onerous.

While we think it ill-advised to call for any cuts in Medicaid prescription drugs, it is with a sense of great urgency and responsibility to the nation's 23 million patients that I ask you to insist that the enactment of any national Medicaid drug discount plan be linked with the removal of all government-imposed drug formularies and other barriers to physician treatment with all FDA-approved prescription drugs.

In closing, I ask you to improve rather than damage Medicaid prescription drug services. Reject S.2605 and other proposals that would deny Medicaid patients access to essential prescription drugs. Only by guaranteeing removal of these restrictions will the right to effective medical treatment for Medicaid patients be ensured.

Thank you.

Statement of

Mark L. Braunstein, M.D.
President and Chief Operating Officer
National Data Corporation

Mr. Chairman and members of the Committee:

I am submitting this statement to you in support of those sections of S.2605 and S.3029 which provide for on-line, real-time pharmacy claims eligibility verification and adjudication at point of sale; and demonstration projects for electronic prospective drug utilization review, and reimbursement for pharmacists' cognitive services. It is my hope that the information contained in this statement will encourage you and your colleagues to include these provisions in H.R.5589.

National Data Corporation (NDC) strongly supports the sections titled "(h) Electronic Claims Management" and "(d) Demonstration Projects" in S.3029 because we believe that these provisions will accomplish three very important objectives: (1) a substantial reduction in Medicaid program costs overall; (2) improved quality of health care; and (3) a substantial reduction in the paperwork and administrative burdens on pharmacists, Medicaid programs and the federal government. This belief is grounded in the experience and success of my company and others in providing point-of-sale (POS), or pre-dispensing, electronic pharmacy claims management to community pharmacies and the health insurance industry.

Several years ago, major insurance carriers began converting from paper claims and computer tape, or post-dispensing, electronic claims processing to the more efficient and less expensive method of real-time POS electronic claims management. Growth in this changeover has been dramatic and continues at a rapid pace, as the vast majority of this nation's community pharmacies are now automated with computer terminals.

For example, NDC over the past year has experienced a 400 percent increase in real-time POS pharmacy claims processed, and is now processing more than 5-million claims per month for a large number of insurance companies and major third-party administrators.

The widespread use of POS claims processing envisioned in the now repealed Medicare Catastrophic Coverage Act of two years ago has clearly come to pass in the private sector insurance industry. The reason is both fundamental and compelling: conversion to POS claims data capture and adjudication means a sharp reduction in costs for the payor, the provider and the consumer as well.

The balance of my statement is devoted to establishing why deficit-ridden Medicaid programs should follow the example of the private insurance industry and begin converting to state-of-the-art claims processing technology and services.

THE NDC MEDICAID INITIATIVE

Shortly after repeal of the Medicare Catastrophic Coverage Act in late 1989, NDC conducted a survey of Medicaid programs to determine whether there was interest in converting to electronic POS claims processing and Pro-DUR. All 51 of the programs requested information on these systems and services.

We were startled, however, to learn firsthand that Medicaid pharmacy programs were continuing to rely on post-dispensing paper and tape claims processing instead of converting to electronic POS claims management. Consequently, some Medicaid pharmacy programs are paying well over $1 for processing a single pharmacy claim, more than double the cost of electronic POS claims processing. We also learned that claim rejection rates were running as high as 25 percent, requiring the added expense of processing these rejected claims a second time. NDC's experience is that electronic POS claims management reduces claim rejections to near zero.

ADMINISTRATIVE COST-SAVING BENEFITS OF ELECTRONIC POS CLAIMS DATA CAPTURE

Large private insurance payors are utilizing real-time POS pharmacy claims data capture to cut administrative costs. These systems and services will likewise reduce administrative costs in Medicaid programs.

1. Electronic POS claims data capture will eliminate paper and tape claims. Using real-time claims data capture, the costs of mailroom, microfilming, scanning, storage, handling, office space, time delay and key data entry are eliminated. It is estimated that approximately 60 percent of the cost of processing a claim can be attributed to these factors.

2. The handling and processing costs for rejected claims will be eliminated. The cost of processing a rejected claim is significantly greater than that of an accepted claim. A return letter must be printed, enveloped and mailed. The provider must then refile the claim and full claims processing costs are incurred a second time. Processing a rejected claim costs between $1 and $2. In a POS environment, the provider is immediately notified through a terminal of any problem with the claim, which permits correction prior to processing. Thus, the cost of processing rejected claims is eliminated.

3. Provider inquiries will be dramatically reduced. It follows that, by eliminating rejected claims through the immediate responses and advisories to the provider via the POS system,

the number of telephone and written inquiries from providers will be dramatically reduced; and, therefore, the cost of staff and resources for handling inquiries could be eliminated.

ADMINISTRATIVE COST-SAVING BENEFITS OF ELECTRONIC POS ADJUDICATION OF CLAIMS

Assuming that POS claims data capture is in place, on-line, real-time fiscal adjudication of the electronically captured claim can be accomplished less than five seconds prior to dispensing. The immediate response feature of the POS system provides a far higher level of control to the Medicaid program or its fiscal agent. This significantly reduces costs, as there is no need for batch processing with associated supervisory and operational staff, tape production and handling and other costs. Full adjudication of an electronic POS pharmacy claim should cost between 5 cents and 25 cents more than the cost of claims data capture, depending on the range of services provided.

USE OF ELECTRONIC FUNDS TRANSFER FOR REIMBURSEMENT

Significant and immediate cost savings to any Medicaid program can be realized through the use of electronic funds transfer (EFT) for reimbursing providers. Most Medicaid programs currently pay claims on a weekly or bi-weekly basis. This involves printing a check and a reconciliation document for the provider, printing and stuffing envelopes, and postage. The total cost of issuing and mailing a check is in excess of $1. Use of EFT for depositing reimbursements directly into a provider's bank account reduces the cost down to 10 cents to 15 cents for each such payment.

CLAIMS-PAID COST-SAVING BENEFITS OF ELECTRONIC POS CLAIMS DATA CAPTURE AND ADJUDICATION SYSTEMS

The potential of these cost-saving benefits is far greater than that from reducing administrative costs. The total cost of the Medicaid program is broken down into administration costs and the actual cost of paid claims. Administrative costs represent less than 10 percent of the total program costs. Therefore, cost containment and cost reduction measures pertaining to claims-paid will affect more than 90 percent of the total program expenditures. Listed below are the major cost reduction opportunities through electronic POS claims data capture and adjudication:

1. Day-specific eligibility verification is provided to the pharmacist via the POS system prior to dispensing.

2. Elimination of good faith payments by Medicaid programs.

3. Reduction of fraud and abuse through the POS system's immediate response to the provider, and concurrent exception reporting on a real-time or daily basis.

4. Elimination of illegal "drug shopping" and fraudulent prescriptions.

5. Enforcement of prior authorization requirements.

6. Plan limitation enforcements such as "days-supply."

7. Lock-in enforcement targets problem recipients or suspected abusers and may require the use of a specific provider only.

8. Benefit plan enforcement and plan design flexibility. This component allows the Medicaid program to alter such benefit plan parameters as quantity and days-supply limits, add to or delete from formularies, or change other plan design parameters with a minimum of cost and description. As the provider is made aware of plan and formulary limitations before the drug is dispensed, such plan design parameters may be changed and become effective immediately.

9. Major improvements in control and cost reporting. Receiving and adjudicating claims on a real-time basis, make it possible for a Medicaid administrator to know at the end of each day or week the number of claims filed, the cost of those claims to the program, types of drugs dispensed, and the kinds of drugs prescribed by individual physicians to individual recipients. Today, due to paper and tape claims, such information is not available for weeks.

10. In addition to fiscal adjudication of claims, electronic POS claims data capture provides the necessary vehicle for performing pre-dispensing prospective utilization review (Pro-DUR). Pro-DUR provides a huge potential for reducing Medicaid costs overall, and will be discussed in detail later in this statement.

The New York Medicaid program has reported an estimated annual savings of $25 to $30 million from its Electronic Medicaid Eligibility Verification System (EMEVS) alone. EMEVS utilizes an electronic POS system to perform day-specific eligibility verification for medical and pharmacy claims. New York intends to phase in pharmacy claims data capture and adjudication.

The Congressional Budget Office (CBO) reportedly has conservatively estimated that, over a five-year period, $195 million could be saved if, by the end of that period, 30 states had converted to electronic POS pharmacy claims data capture and adjudication.

THE NEED FOR PROSPECTIVE DRUG UTILIZATION REVIEW IN MEDICAID

The CBO analyzed potential savings from demonstrations of pre-dispensing prospective drug utilization review (Pro-DUR) provided for in Senator David Pryor's legislation, and reportedly estimated that Pro-DUR could save more than $557 million over a five-year phase-in of 30 state Medicaid programs.

There is a critical need for Pro-DUR in state Medicaid pharmacy programs in order to prevent life-threatening adverse drug reactions and interactions, as well as to reduce costly waste.

Inappropriate prescribing has come to be known as our nation's "other drug problem."

A recent study by the Inspector General, U.S. Department of Health and Human Services, reports that "Nearly every prescription written in 1988 by physicians who graduated from medical school in 1960 is for drugs about which those physicians have received no formal education." The Inspector General also cited an earlier study conducted by researchers at Temple University Medical School, which showed that more than 70 percent of a group of physicians surveyed failed a test on knowledge of prescribing for the elderly.

Moreover, government-sponsored and university-based studies have shown conclusively that individuals, especially the elderly, who suffer from multiple illnesses and take multiple medications prescribed by two or more physicians often are victims of inappropriate, and sometimes dangerous, drug prescriptions.

Preliminary findings of a study by researchers at the University of California at San Francisco indicate that 87 percent of a group of elderly patients discharged from the hospital with at least three prescriptions had one or more clinically significant medication problems. Findings also suggested that 22 percent of the patients received a drug that could have been life-threatening, or could have led to rehospitalization.

The Public Citizen Health Research Group's (PCHRG) recently published study, "Worst Pills Best Pills," estimates that in 1985 "243,000 older American adults (60 and older) were hospitalized because of adverse reactions to drugs they were taking before their hospitalization. PCHRG further estimates that each year:

- "More than 9 million adverse drug reactions occur in older Americans;
- "32,000 older adults suffer from hip fractures attributable to drug-induced falling;
- "163,000 older Americans suffer from serious mental impairment (memory loss, dementia) either caused or worsened by drugs;
- "2 million older Americans are addicted or at risk of addiction to minor tranquilizers or sleeping pills because of using them daily for at least one year; and
- "73,000 older adults have developed drug-induced tardive diskinesia [uncontrollable and involuntary movements and shaking], the most serious, common, and often irreversible adverse reaction to antipsychotic drugs."

Harvard researchers reported in late 1988 on the use of psychoactive medications in a representative sample of intermediate care nursing homes in Massachusetts. They found that over half of the 850 residents in these nursing homes were taking a prescribed psychoactive drug, including antidepressants, sedative/hypnotics, and powerful antipsychotics.

A study conducted by Vanderbilt University researchers in 1986 revealed highly inappropriate and excessive prescribing of powerful and potentially dangerous antipsychotic drugs for elderly nursing home residents in Tennessee. Almost 40 percent of 20,500 duly eligible Medicaid/Medicare nursing home residents between the ages of 65 and 84 were prescribed these incapacitating medications which are normally used for treating schizophrenia in younger individuals.

In 1988, a report by the Special Committee on Aging of the U.S. Senate stated that, in 1986, "as many as 120 million prescriptions [for elders] costing more than $2 billion" may have been "inappropriate." The report emphasized the need for a computerized electronic Pro-DUR system to reduce prescribing of addictive and powerful tranquilizers and antipsychotic drugs for the elderly, especially those residing in nursing homes.

Pharmacists have long practiced prospective drug utilization review as an integral part of quality assurance and prevention of drug-induced adverse reactions. Pro-DUR, however, has become increasingly important because of dramatic growth in drug therapies over the last half century.

Physicians now have more than 10,000 prescription drugs from which to choose in treating their patients. Consequently, most physicians find it extremely difficult, if not impossible, to keep abreast of the latest information on the thousands of potential adverse drug reactions and interactions associated with this huge and growing assortment of drugs.

The interdisciplinary working relationship between the prescribing physician and the dispensing pharmacist, therefore, has taken on increasing importance in detecting potential adverse reactions before a drug is dispensed. Fully cognizant of this responsibility, pharmacists for years have kept close at hand such comprehensive compendia as the U.S. Pharmacopea "Drug Information for The Health Care Provider," and the "Hospital Formulary." These voluminous reference compendia contain information on appropriate prescribing of medications, and precautions and warnings concerning potential adverse effects of certain drugs taken by themselves or in combination with other drugs.

Potentially severe drug interactions alone number in the thousands, not to mention allergic and cross-sensitivity reactions, harmful drug-to-illness/condition effects, and reactions to incorrect dosage. As the number of new drugs continued to grow, day by day, so did the amount of time spent by the pharmacist to insure safe and appropriate drug dispensing. Pharmacists needed a quick, efficient and accurate way of retrieving this information which is so crucial to their patients' welfare, especially the elderly. Computer technology has provided the solution.

In addition to performing pre-dispensing fiscal adjudication of claims, real-time electronic POS systems can be used simultaneously to assist the pharmacist in performing comprehensive clinical adjudication, or Pro-DUR. Systems in use and under development can perform all of the functions mandated for the 10 statewide demonstrations of Pro-DUR in Senator Pryor's legislation, and more.

THE NEED TO REIMBURSE PHARMACISTS FOR COGNITIVE SERVICES

I believe it is essential for us to appropriately and fairly compensate the pharmacist for providing cognitive services in dispensing drugs.

There is universal acceptance of cognitive reimbursement in the practice of medicine. The examining physician receives a fee, regardless of whether the patient is sick or not.

The pharmacist, however, who may spend considerable time evaluating the appropriateness of a prescription, only receives a fee of three or four dollars if the prescription is filled and dispensed. But the pharmacist receives no compensation if he/she determines that the prescription is inappropriate and, in the interest of the patient's safety, declines to dispense the medication.

The pharmacist traditionally has served as "gatekeeper" in determining whether a prescription is appropriate and safe prior to dispensing. It would, therefore, seem more equitible and prudent for the pharmacist to receive a cognitive reimbursement for declining to dispense a medication that could do serious harm to the patient.

The provision for a "Demonstration Project On Cost-Effectiveness Of Reimbursement For Pharmacists' Cognitive Services" is an important beginning toward fulfilling the need to fairly and adequately compensate practicing pharmacists as health care providers.

THE TASK AHEAD

I am confident that other private sector providers of real-time POS pharmacy claims management as well as NDC would welcome the opportunity and privilege to assist state Medicaid programs in implementing these state-of-the-art technologies and services.

Moreover, I am certain that our industry's years of experience in developing computerized health care management systems and services would serve exceptionally well toward establishing and maintaining optimal economy and quality assurance in state Medicaid pharmacy programs.

Mr. Chairman, the question to be addressed in the face of a growing deficit crisis, on both the federal and state levels, is upon us. Can we permit this enormous and needless expense in Medicaid pharmacy claims processing to continue, when more than 31 million Americans are without Medicaid or any other type of health insurance?

I, therefore, urge you and your colleagues to incorporate into H.R.5589 the provisions for "Electronic Claims Management" and Demonstration Projects" as contained in S.3029.

TESTIMONY

Robert H. Barr, M.D., R.Ph.

Assistant Director, Harris County Health Department

and

Chairman, Vendor Drug Advisory Subcommittee
Medical Care Advisory Committee
Texas Department of Human Services

Mr. Chairman, my name is Robert H. Barr. I am a physician and have a degree in pharmacy. I have been assistant director of the Harris County Health Department since February 1987, and I am chairman of the subcommittee of the Medical Care Advisory Committee that recommends which drugs should be included on the state's Medicaid formulary.

Since S.2605 and other proposals before your committee would require Texas to adopt a Medicaid formulary written by consultants in Washington, D.C., I felt it was necessary to defend the present system and the program that's now in place in Texas. It works very well and consequently is supported by most of the state's physicians. I am afraid that if the restricted formulary envisioned in S.2605 is forced on our physicians, there won't be any Medicaid providers left in Texas.

Recently, the Texas Department of Human Services sent to your committee its comments on S.2605, developed by the Deputy Commissioner for Contracted Client Services, Dr. Donald L. Kelley. Let me summarize these comments briefly:

1. As a charge-based system, the proposal is inherently inflationary. Pharmacists' customary charges are often far higher on drugs, particularly generic drugs, than is warranted by the ingredient costs. Mandating such a system in Texas would result in a 6% ($10-$12 million per year) total loss to the program, along with $2.5 million per year in increased audit costs. Also, future customary charges would be pushed higher than the average 9% annual increases as drug manufacturers "cost shift" the losses from Medicaid to the private paying customer.

2. Since the bill's savings estimates from rebates are unlikely to be realized, Texas' open — and broad — formulary will have to be restricted in order to generate any savings. Extensive physician overrides, which are likely with any restricted formulary that permits them, would negate the majority of such savings.

3. To be allowed to continue its current system, the Texas Medicaid program would have to achieve approximately 15% savings in drug product cost over what it currently pays. Texas has already implemented "estimated acquisition cost" (EAC) drug pricing policies, so our state is placed at a substantial disadvantage over states that have continued to pay "average wholesale price" (AWP) for drugs. For example, on a $10 AWP drug product, a state such as Arkansas need only negotiate on $8.50 real drug product cost (after rebate) to comply with the law, whereas Texas -- where EAC policies mandate payment close to the pharmacists' actual cost of approximately $8.70 for the same drug — would have to negotiate a real price, after rebate, of $7.40 in order to be in compliance.

4. A stated objective of S. 2605 is to increase pharmacists' fees. As Dr. Kelley noted, S.2605 can best be described as a reimbursement system that would "rob Peter to overpay Paul." Incidentally, pharmacy organizations are about the only public support Senator Pryor has for S.2605, which is not surprising.

Let me reemphasize a point made by Dr. Kelley: Texas' highly successful system of reimbursement to pharmacies, which has been developed over the past five years, evolved in a climate of State/Federal partnership and program flexibility. Our system has resulted in a broad, stable provider population and excellent access to services. There seems to be little logic in removing all state flexibility in pharmacy reimbursement, which will negate established program savings. Savings attributable to drug rebate programs should be in addition to current program savings rather than instead of them. States should retain the flexibility to work with all the participants in the prescription market place to capture all potential savings from Medicaid programs.

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